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AD NUMBER
ADB259790
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AUTHORITY
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AD _____

Award Number: DAMD17-99-1-9575

TITLE: GuideLine Interchange Format (GLIP): Extensions and
Practical Applications

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REPORT DATE: September 2000

TYPE OF REPORT: Final Proceedings

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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OMB No. 074-0188

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1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE September 2000	3. REPORT TYPE AND DATES COVERED Final Proceedings (1 Sep 99 - 31 Aug 00)	
4. TITLE AND SUBTITLE GuideLine Interchange Format (GLIP): Extensions and Practical Applications			5. FUNDING NUMBERS DAMD17-99-1-9575	
6. AUTHOR(S) Aziz A. Boxwala, M.D., Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Brigham and Women's Hospital Boston, Massachusetts 02115 E-MAIL: aziz@dsg.harvard.edu			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Distribution authorized to U.S. Government agencies only (proprietary information, Sep 00). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012.				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) A workshop titled "Toward a Sharable Guideline Representation" was held in Boston on March 3-4, 2000. Approximately 200 people represented 11 countries and various stakeholders including those from academic medical informatics, healthcare provider organizations, professional societies, government, and informatics industry. The purpose of the meeting was to identify needs for guidelines and sharing guidelines, develop robust representation models, and establish a process that fosters sharing. The meeting consisted of two plenary sessions and two breakout sessions of five groups. The topics for breakouts were Functional requirements, Representation models, Special needs of clinical trials, Infrastructure and tools, and Organization and process. Two page position statements were invited from participants prior to the meeting. All of these statements were published on the Internet prior to the meeting and hardcopies distributed during the meeting. Slides from speakers in plenary and breakout session are also published on the Internet (http://www.glif.org). The meeting resulted in increased discussions among interested parties on sharing of guidelines. Email discussion groups were created on the topics of the breakout. Discussions with HL7 were conducted and resulted in the formation of the HL7 Special Interest Group on Guideline Interchange Format.				
14. SUBJECT TERMS Clinical Guidelines, Knowledge Representation, Standards			15. NUMBER OF PAGES 110	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

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Introduction

Clinical practice guidelines and protocols are being applied in diverse areas including policy development, utilization management, education, reference, clinical decision support, conduct of clinical trials, and workflow facilitation. Many parties are engaged in developing guidelines, an arduous task with much redundancy and overlap among the resulting products, but there is little standardization to facilitate sharing or to enable adaptation to local practice settings. Yet considerable progress has been made on developing approaches to addressing these issues, and standardized approaches for guideline representation and sharing are central to these efforts.

To address these issues, a workshop titled "Toward a Sharable Guideline Representation" was organized in Boston, MA on March 3-4, 2000. This workshop focused on:

- the issues, applications, and purposes for guideline use in order to ensure that a standardized representation is sufficiently robust to address these purposes
- the technical requirements for such a representation
- the establishment of a multi-stakeholder group process for achieving these goals.

This workshop brought together stakeholders representing academic medical informatics, health care payers, professional specialty organizations, health care providers, the Federal government, and the health care information industry, from both the US and abroad.

Invited speakers and discussion leaders facilitated the workshop process. Initial plenary talks provided background on a variety of work and accomplishments to date, the needs, and the charge to the workshop participants. Breakout groups then focused on issues of functionality, sharable representation approach, and organizational issues of a guideline-sharing framework. The output of the meeting was a set of position statements, a proposed organizational structure, and increased collaboration and discussion amongst interested parties using e-mail discussion groups.

Body

The workshop was organized by

Aziz Boxwala, MBBS, PhD (co-chair)

Lucila Ohno-Machado MD, PhD (co-chair)

Robert A. Greenes, MD, PhD

Edward H. Shortliffe, MD, PhD

The agenda consisted of two plenary sessions followed by breakouts. The plenary sessions were intended to provide an overview of the guideline representation efforts to date and to have background talks on related topics.

The table below lists the presentations in the first plenary session.

Robert A. Greenes	Purpose of the workshop
Edward H. Shortliffe	Motivation for structured guidelines
Aziz A. Boxwala	Functional requirements of guideline representation and use
Robert Jenders	Arden Syntax
Mor Peleg	Contrasts between modeling approaches for clinical guidelines and medical decision rules
Vimla Patel	Cognitive issues in guideline representation and use
Lucila Ohno-Machado	Description of breakouts

The second plenary period was split into two sessions: *technical* and *non-technical*

Topics presented in the technical plenary session were:

Dan Russler and Gunther Schadow	Developing Guideline Messages Using the Clinical Classes in the HL7 Reference Information Model
John Fox	Guardian agents: the PROforma approach to quality and safety of interactive guidelines
Colin Gordon	PRESTIGE: An approach to shareable guidelines proven in 6 EU countries
Lucila Ohno-Machado	GLIF 3
Mario Stefanelli	From Guidelines to Workflows
Samson Tu	Toward a Task-Specific Component-Based Guideline Modeling Architecture: The EON Approach

Topics presented in the non-technical plenary were:

Christel Mottur-Pilson	Development and Dissemination of Guidelines
Johan van der Lei	Garbage in, Garbage out: The importance of well-designed practice guidelines
Jose Arocha	Interpreting Guidelines Using Propositional and Semantic Analyses: Implications for authoring tools
Alexa McCray	Developing a national clinical trials registry
William Yasnoff	Presenting CDC Guidelines at the Point of Clinical Decision
Keith Campbell	Terminology: one size does not <i>currently</i> fit all

There were five breakout sessions that consisted of initial brief presentations followed by group discussions on focused topics. The breakout groups reported back to the joint session. The following is the summary of the five breakouts:

Breakout Topic: Functional Requirements

Discussion leader: Perry Miller, Daniel Kent

Recorder: Edward Shortliffe, Mor Peleg

Goals/Subtopics:

Although many groups have individually worked on defining the design criteria and functional requirements for a computer-based representation of clinical-guidelines, most such efforts have been guided by local, application-specific considerations. In this breakout session we will try to generalize the specification of such criteria and requirements, working from the experiences of the individuals involved and from draft documents and position papers that have proposed the range of guiding principles for a guideline representation language. Issues for discussion will include:

- What are the types, applications, and use environments of guidelines?
- What are the key elements that must be included in a computer-based representation for guidelines?
- What does it mean for an encoded guideline to be computable?
- What levels of abstraction best serve the process of authoring and understanding clinical guidelines?
- How should ambiguities be managed?
- How should a representation deal with decisions for which the evidence is absent or conflicting?
- What kind of support is required for viewing and comprehending the logic of a clinical guideline?
- How should a representation best support local adaptation and implementation of a clinical guideline?

Breakout Topic: Model and Representation

Discussion leader: John Fox, John Gennari

Recorder: Aziz A. Boxwala, Qing Zeng

Goals/Subtopics:

The discussions in this breakout session will focus on issues of knowledge representation including knowledge modeling and representation formats. Topics for discussion include:

- Paradigms for representation of guideline knowledge (such rules, frames, probabilistic methods, etc)
- Formats for sharable guidelines

- Technical issues in interfacing with complementary standards such as for messaging (e.g., HL7), vocabularies (e.g., SNOMED-RT)
- Technical issues in integration with extant knowledge representation formats 5. Issues in linking to electronic medical records 6. Methods for assuring quality and safety of content

Breakout Topic: Special Issues Relating to Clinical Trials

Discussion leader: Alexa McCray, Carol Broverman

Recorder: Lucila Ohno-Machado, Samson Tu

Goals/Subtopics:

Clinical trial CT protocols are distinguished guidelines that share many features commonly found in other clinical guidelines. However, they are often described to be more deterministic than standard-of-care guidelines. This distinction is due to the nature of research studies, the trials authoring and approval process, and the well-defined and regulated data gathering requirements associated with clinical trials. Sponsors and the conducting sites also have different views of the protocol that must be supported. The representation and management of clinical trials in a computerized setting must also accommodate the dissemination of updates, amendments and revisions to the protocols.

The goal of this session is to focus on the special needs to support clinical trials management, ranging from representation requirements, functional requirements, and infrastructure requirements. What are the distinct differences between clinical trial protocols and clinical guidelines?

Topics for discussion:

- CT protocols: Overall structure and requirements
- CT protocol modeling and workflow management
- CT eligibility criteria
- CT adverse events and randomization
- CT common data elements (NCI)
- CT site and sponsor requirements
- CT conditionality and decision-making
- CT temporal issues

Breakout Topic: Infrastructure and Tools

Discussion leader: John Silva, Chip Masarie

Recorder: Omolola Ogunyemi

Goals/Subtopics:

It is clear that guidelines and protocols, used during patient encounters, significantly reduce the risk to both patient and physician. It is also abundantly clear that, unless these guidelines and protocols are transparently used within the encounter, most physicians don't or won't use them.

How to get more physicians and / or patients to use tools is a central issue. It is attractive to imagine that guidelines or protocols could, some day, “self install” within the infrastructure of the physician’s office and become an integral component of care delivery processes.

The National Cancer Institute, as well as other national-level organizations, have an even greater challenge: how do they publish a text document that specifies a practice guideline or clinical trial and generate the computer-readable specifications that would permit the trial to be installed in ANY authorized place of practice? This includes cancer centers, cooperative groups, smaller community cancer centers, oncology practices, etc. This track will explore

1. how to generate computable specifications for a clinical trial [or guideline],
2. what tools and infrastructure are needed on the generating end
3. what tools and infrastructure are needed on the receiving end
4. how to maintain trials content between ALL the sites and the originator, specially for updates, amendments, revisions, etc
5. what is the architecture needed
6. what should/could be the first set of experiments

Breakout Topic: Creation of a process for standardization of a guideline

Discussion leader: Daniel Kent, John Dulcey

Recorder: Robert A. Greenes

Goals/Subtopics:

To continue the work of converging various initiatives toward a standardized approach to representation and sharing of clinical guidelines, an organizational entity needs to be charged with that responsibility, the various stakeholders must be actively involved, key individuals must be committed to this activity, and the process must have a means for financial support for this continuing work. Issues to be considered during this breakout session include but are not limited to the following:

- What organizational form is most appropriate, e.g., independent non-profit consortium, alignment with or subgroup of an existing SDO?
- What activities should the entity take on, e.g., white papers, standards documents, meeting sponsorship, open source software tool repository and distribution?
- What kinds of membership should the entity have, e.g., individual vs. institutional, or both, what privileges associated with each?
- What are means for supporting the entity's ongoing activities, e.g, grants, membership fees (possibly tiered)?

Key Research Accomplishments

The meeting accomplished its primary objective of initiating a dialog on issues on sharing of computer-based guidelines. The presentations from the workshop and the summaries of the breakout sessions are attached in the appendices. These may also be accessed from www.glif.org.

Following the meeting, e-mail listserv discussion groups were organized. Five groups were started, one for each of the breakout sessions. Information on how to subscribe to these lists is available at www.glif.org.

Following the meeting a dialog was initiated with HL7 organization to examine how the process of standardization of a format for shared guidelines should be accomplished. In September 2000, the HL7 Board approved of the formation of a Guideline Interchange Format Special Interest Group. The GLIF SIG is part of the Decision Support Technical Committee of HL7. The mission of this SIG is "... to create the standard electronic representation for the specification of clinical practice guidelines for purpose of interchange and to facilitate their integration into the healthcare systems, computer-based medical records, and a variety of applications."

Reportable Outcomes

Key outcomes of the meeting are

1. Eighty attendees participated in a 2-day workshop aimed at fostering sharing of computer-based guidelines and developing representations for shared guidelines (Appendix A)
2. Thirty-one position statements were submitted for the workshop and published on the Internet at www.glif.org (Appendix B)
3. Each breakout group created a summary of its discussions that outlined the problems to be addressed, priorities, future plans, and parties that would be appropriate for working on these issues in the future. These summaries are published on the Internet. (Appendix C)
4. The functional requirements breakout group produced a fairly comprehensive set of functional requirements for a shared guideline representation. (Appendix D)
5. Presentation on the workshop was made at the Annual Meeting of the American Telemedicine Association in Phoenix, Az in May, 2000.
6. E-mail listservs were created to facilitate continuing discussions on these topics.
7. Formation of the GLIF SIG in HL7 as a consequence of post-workshop discussions with the HL7 leadership.

Conclusions

The workshop brought together several of the key stakeholders to address issues of sharing clinical guidelines and develop representations for shared guidelines. There was a strong consensus among participants that this topic is important and that work on it should continue. The workshop was crucial in initiating discussions that will continue in other forums (electronic, HL7, scientific and industry conferences). We expect that these discussions will produce a process and standard for representation of shared guidelines.

References

None

Appendix

- A. List of registered attendees at the workshop
- B. Position statements submitted for the workshop
- C. Summary presentations from breakout groups
- D. Functional requirements for a shared guideline representation

Appendix A

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Appendix B

Position Statements

Paper Title	First Author
Construction of a Semantic Meta-vocabulary on Sharable Guideline Representation	Marivan Abrahao
Terminology and Information Model Requirements for a Shared Guideline Model	Carol A. Broverman
Supporting a unified quality and safety methodology for enactable electronic guidelines	Jonathan Bury
An ontology-driven approach for the acquisition and execution of clinical guidelines	Paul de Clercq
Perspectives from guideline implementation in a diabetes disease management application	Anil K. Dubey
Guideline Integration Requires an Underlying Common Representational Schema	Peter L. Elkin
Representations for sharable guidelines: convergence or diversity?	John Fox
Representations for Sharable Guidelines	Colin Gordon
Clinical Guidelines Representation: Incrementally Beyond Arden Syntax	Robert A. Jenders
Primary Care Chronic Disease Guidelines	Peter Johnson
Knowledge Representation of Situation-Specific Clinical Practice Guidelines	Ronilda C. Lacson
Contraindications and Negative Recommendations	Ronilda C. Lacson
A Life Cycle Model for Clinical Practice Guidelines	David F. Lobach
Clinical Decision Support: MedicaLogic Position	Chip Masarie
Common Data Elements for a Clinical Trials Registry	Alexa T. McCray
Maintaining the Knowledge in Computer-Based Clinical Guidelines: A Challenge for the Future	Perry L. Miller
Untitled	Richard Moberg
Development and Dissemination of Guidelines	Christel Mottur-Pilson
Representing Uncertainty in Clinical Practice Guidelines	Lucila Ohno-Machado
Propositional Representation of Clinical Practice Guidelines	Vimla L. Patel
Usability Analysis of Guideline Encoding and Application in Clinical Practice	Vimla L. Patel
Use of Clinical Practice Guidelines: Lessons from Research at the Point of Care	Vimla L. Patel
The role of ontologies for an effective and unambiguous dissemination of guidelines.	Domenico M. Pisanelli
Integrating Guidelines into the HL7 Reference Information Model	Gunther Shadow
GEM: A Guideline Document Model Using XML	Richard N. Shiffman
Clinical Practice Guidelines: Principles for Life Cycle Systems Engineering	Barry G. Silverman
Consistency of Clinical Guidelines	Oleg Sokolsky
Untitled	Mario Stefanelli
Integrating Guidelines in Clinical Practice Using Electronic Medical Records	Paul C. Tang
Modeling Guidelines and Protocols: A Task-Based Approach	Samson Tu
What's in a protocol	J. van der Lei

Construction of a Semantic Meta-vocabulary on Sharable Guideline Representation

Knowledge representation has always been a challenge on the development of Health Information systems. Despite of an implicit definition on a sharable guideline representation, and somewhat explicit on the structure of the guideline model of the GLIF format, some questions emerge from the *evaluation of the type of information* that is intended to be shared among computer medical systems.

As mentioned in some studies, the translation of unstructured data from existing guidelines into structured representation format imposes an extra vigor and an inconvenient jeopardy to data quality. Also, most of cognitive-evaluation techniques are incipient tasks while dealing with natural language processing.

The absence of an altered univocal procedure between a text-based guideline and GLIF format (one text guideline can generate several GLIF-based guidelines) arises an insufficient semantic scope about the quality of the shared information.

Expressing a structured guideline without ambiguity forces a construction of a semantic meta-information vocabulary over the information acquired during the translation process. This new vocabulary should describe the wholeness of the expected information by the system and also information originated throughout this process, including support for general and international measurement conventions systems (i.e., weight, height, temperature, etc.), medical codification (ICD-9, ICD-10, SNOMED, etc.) and different language endorsement (i.e., Portuguese, French, Spanish, etc.).

For instance, an unstructured data (i.e. fever) translated into structured format (i.e., temperature > xx) should be notarize from this meta-vocabulary (i.e., Celsius or Fahrenheit) to strengthen the comprehension of the information and enrich the uniqueness of encoding process.

Nevertheless, the problem of relying subjectively on the encoder knowledge will persist, as semantic reasoning depends on medical background knowledge.

Furthermore, a special attention should be rendered to the development of on-the-fly translators systems to shorten the processing path and minimize the conflict between formal data interpretation and subjective meanings of guideline representation.

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Terminology and Information Model Requirements for a Shared Guideline Model

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One of the primary obstacles in establishing widespread acceptance of any decision support system is the difficulty in integrating such a system into the patient care workflow and existing information systems. Deployments of such systems always require extensive work efforts to build institution or database-specific conduits to deal appropriately with local schemas, data types, and vocabulary terms. The effort required to integrate a new system into an existing infrastructure represents both a significant start-up and maintenance resource cost to the institution; and a nearly insurmountable barrier to technology sharing across institutions, technologies, and vendors.

The work to date on knowledge-based guideline and rule standards (specifically GLIF and the Arden Syntax) has concentrated on the modeling of clinical rule and guideline logic from a process and knowledge model perspective. A critical piece of the puzzle that has understandably been sidestepped is the integration of patient-centered data elements and the accompanying "terminology integration." A typical approach taken within guidelines developed by the collaborators is the use of predicates and other constructs to reference clinical concepts within a locally-defined ontology, a solution which is not shareable. This missing piece is what has been referred to as the infamous "curly braces" problem within the Arden Syntax community [1]. The reason for this position has been the lack of an agreed-upon information model for patient information and clinical concepts, and a lack of a unified medical terminology by which specific clinical concepts can be uniquely identified.

It is our position that solutions to this issue should leverage ongoing work within other standards bodies that include representation from all of the following areas: academic medical centers, government sponsored work groups, and the industry sector. Specifically, we believe that Health Level Seven (HL7), an ANSI approved standards body, has become a locus of activity that brings together these different interest groups. Within this framework, we suggest the consideration of a strategy to devise data query constructs in the guideline model that is consistent with the Reference Information Model (RIM), the HL7 Version 3.0 data types, and the "value domain specifications" currently being devised within various HL7 committees.

Previous work reports on the use of the HL7 Reference Information Model to address the infamous "curly braces" problem within the Arden Syntax [2]; a problem which persists within the usage of GLIF and other related formalisms in the various institutions of the InterMED collaboratory today. We believe that since this initial report, the work on the RIM has undergone numerous iterations and harmonizations, and has evolved into a more broad-based work that also incorporates constructs to support guidelines. This work represents the collaborative work of the Patient Care Technical Committee and the Orders and Results Committee, and has culminated in the incorporation of the resultant Unified Service Action Model (USAM) into the RIM [3].

Furthermore, it is possible to specify data type and terminology constraints within guidelines and protocols by using the data types and syntactic terminology domain specifications being developed by the Control/Query and Vocabulary Technical Committees within HL7 [4]. For example, standardized qualifiers such as *domain name* (e.g.; Clinical Diagnosis), *realm* (e.g.; USA), and *code system* (e.g.; SMI for SNOMED International) as catalogued in a *Value Set Definition Table* could be referenced within a guideline. These qualifiers, along with a particular clinical expression could be passed to a terminology server to resolve.

We also advocate that the information representations and data dictionaries being developed by other related organizations be registered in a central repository with other terminologies such as SNOMED-RT, MedDRA, ICD-9-CM, LOINC, and others, and harmonized/mapped where possible. Examples of such other related efforts are the Common Data Elements (CDE's) being produced by the Cancer Information Infrastructure (CII) of the National Cancer Institute (NCI) [5], and the glossary, meta-model and other workproducts being produced by the Clinical Data Interchange Standards Committee (CDISC -- a working group within the Drug Information Association (DIA) [6]). For example, it might be possible to fold in the work on Common Data Elements within the CII/NCI into a more rigorous data model that could be a subset of vocabulary "registered" within the HL7 framework.

Other possible areas for collaboration and advance would involve standardizing the language of eligibility criteria. This language would create associations to a centralized bank of terminologies, using the standardized syntactic expressions for terminology domains. This proposed project would bring together related on-going work at universities, NCI, NLM, CDC and FDA. The involvement of industry would be needed to appropriately tech-transfer this work and bring about a wider deployment of a "terminology-enabled" guideline and protocol standard.

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Supporting a unified quality and safety methodology for enactable electronic guideline

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Introduction

The development of traditional, paper-based methods for disseminating guidance on best clinical practice has been accompanied by the development of accepted processes for ensuring the quality of the information published. The current development of new paradigms for the electronic dissemination and consultation of clinical material - including enactable clinical guidelines and decision support systems - must also be accompanied by the development of appropriate new methods for ensuring the quality and safety of the resultant systems.

A distinction should be drawn between the *clinical validity* of the content of a decision support application, and technical aspects of the representation and delivery of that content. A unifying methodology for quality assurance will need to embrace approaches from at least 4 different areas:

- documentation standards to support clinical quality and accountability
- a rigorous publishing and evaluation cycle supporting the medical content and its evidence base
- software engineering methods to support application integrity / reliability
- the development of software capable of supporting active safety management and dynamic management of unforeseen hazards

Mechanisms for ensuring the quality of the clinical knowledge base

One approach to quality assurance is the use of documentation fields, such as the "Maintenance" and "Library" slots used in the Arden Syntax Medical Logic Modules. We propose to extend this approach to differentiate between clinical concerns, such as validity, applicability, and authorship, and technical concerns such as version control and interoperability.

We believe that the use of such documentation fields also needs to be complemented by a structured development and reappraisal process, paralleling that used by the pharmaceutical industry in evaluating new drugs. The validation of an application on test cases ("paper patients") might be the first step in this process, but would represent only the start of a continuing validation and refinement cycle. In such a cycle, data on the impact of guideline use on clinical outcomes would be fed back systematically into the authoring process. Use of Electronic Patient Record and statistical analysis and data mining techniques will facilitate the discovery of more complex relationships between patient presentations, clinical interventions and clinical outcomes than is feasible at present. In effect, every patient treated according to an electronic clinical guideline is automatically entered into an ongoing clinical trial of that guideline, with immediate potential to collect and analyse data in real time.

Mechanisms for ensuring the safety and reliability of the delivery technology

The efficacy of individual applications cannot be considered in isolation; in our view we also have an obligation to show, as far as possible, that *the general techniques are formally sound and that the technology is safe* (Fox and Das, forthcoming). There has been growing interest in applying techniques from formal software engineering to decision support systems in recent years. The motivation for developing formal design techniques has been both the desire to remove many of the apparently *ad hoc* practices associated with decision support systems development, and to provide techniques for automated verification and validation of the system knowledge base.

We have also argued that in complex domains like medicine even the most rigorous design, validation and verification will not guarantee that clinical misadventures will not occur in practice. It is humanly impossible for software designers to anticipate all the hazards that can arise due to unforeseen and unforeseeable interactions that may occur in the pressures of routine clinical medicine. We therefore believe that medical informaticians must address dynamic as well as static aspects of the system design. The approach that we are adopting is to incorporate active hazard management systems into the guideline delivery technology. These "guardian agents" are intelligent systems in their own right but their expertise, the detection and management of hazards, is complementary to the medical knowledge which is encoded in the guideline itself (Fox and Das, *op cit*).

	Application development stage	Application deployment stage
Clinical content	Medical documentation including : <ul style="list-style-type: none">• Content authorship• Degree of validation• Links to further information• Test cases used during validation, or other evidence supporting validation status	Structured lifecycle methodology, supporting the feedback of clinical outcomes into content revision.
Technical platform	Software design : <ul style="list-style-type: none">• CASE tools for authoring, checking and testing• Use of a formally grounded interchange format Technical documentation including : <ul style="list-style-type: none">• Guideline logic• Design rationale	Support for software methods capable of actively anticipating problems, and responding to unforeseen hazards.

Table : Key features of a proposed unified quality and safety methodology, providing support for clinical and technical quality assurance, during the development of applications and during their operational lifecycle.

Reference

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ON IMPROVING KNOWLEDGE REPRESENTATION AND FUNCTIONALITY OF A SHARED GUIDELINE FORMAT: Perspectives from guideline implementation in a diabetes disease management application

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Introduction

With the increased emphasis in applying evidence based medicine to everyday care, there has also been a renewed interest in clinical practice guidelines. Computerized guidelines have been shown as an effective means of improving guideline compliance¹⁻⁴. While developing a guideline engine for a diabetes operations improvement, we decided upon a representation based on the GLIF – the GuideLine Interchange Format⁵. Others have also studied and used GLIF as well⁶⁻⁹. We chose this formalism because it can be easily (and exactly) represented in a flowchart, a representation familiar to clinicians. This was a significant advantage in developing the guideline content with computer-naïve clinicians. While building this system, we encountered limitations in the GLIF specification. These limitations, while not so apparent in the static version of guideline content, became readily so in the context of real world implementation. These limitations can be described as being in one of four categories: incomplete and missing data, interactive versus batch (or daemon) mode execution, mapping of data elements in guideline steps to outside data sources, and structuring of guideline output. In this position statement, we will describe each of these categories in more detail, and briefly mention how we addressed them.

Incomplete and missing data

Data availability is a significant factor in implementing computerized guidelines. In the context of the diabetes operations improvement project, it became immediately apparent that missing data items would be a common occurrence. In thinking about missing data and its impact on specific guidelines, we made 2 observations. First, that not all data items have the same importance; some data elements are more significant than others. While some missing data elements might cause a guideline's execution to halt, others may not. The second observation we made was that, in general, the more information you have, the more specific advice you can derive from a practice guideline. Thus, even if the execution of a guideline did stop, some advice (albeit more general) could still be given. To incorporate these observations into our implementation, we did the following: first, we used a tri-value logic scheme (true/false/unknown). Situations where not all data elements were known would result in an "unknown" value. Second, we extended the logic of the guideline's execution model such that it would handle the third "unknown" value properly. Third, we incorporated within the framework of our implementation the ability to "remember" all unfulfilled data requests, such that they could be returned to the client app (along with output advice).

Interactive versus batch (or daemon) mode execution

Computerized guidelines can be executed in one of two modes: in an "interactive" mode, where there is a human user that can fill in missing items (i.e. a guideline system within an order entry system), or in a "batch" mode, where the guideline is running as a background process (i.e. a guideline system that prints reminders on a summary page prior to a clinic visit). In the latter situation there is no human user to supply missing data. A sharable guideline formalism should be able to handle both contingencies.

In our implementation, we treated GLIF steps as functions that take as input and return as output a "data tree object." This data tree object represents the "state" of the guideline engine at any given point. As guideline execution progresses from GLIF step to GLIF step, this "data tree object" is chained from one GLIF step to another. Because this "data tree object" stores the 'state' of the guideline system, all that would be required to change the mode of execution from batch-mode to interactive mode would be to pass this object to a user interface before it goes to the next GLIF step.

Mapping of data elements in guideline steps to outside data sources

This is a significant problem; in one experiment involving sharing of Arden Syntax encoded MLM's, most had to be modified; the most frequently modified area was the "data" section¹⁰. This data mapping problem in MLM's is often referred to as the "curly braces" problem (because the data section in Arden Syntax is denoted by curly braces). Ideally, the implementation-specific details of data acquisition should be encapsulated from the logic specification of the guideline. The initial version of GLIF provides no systematic formalism for representing these data-mapping issues. In our implementation, we encapsulated the "logic" portion of the guideline engine from the "data acquisition" part by using an XML-based interface. We chose XML because at the time it was an emergent web-based standard; in theory any scheme capable of supporting hierarchical data structures would suffice.

Structuring of guideline output

We came to the conclusion that the output from a guideline engine should be structured. We arrived at this conclusion from multiple perspectives. First, within the context of the diabetes project, we needed to have 2 views of the guideline recommendations: a "headline" view, and a more detailed "drill-down" view. Second, from examining the GLIF standard, it became apparent that in order for GLIF to truly support nested subguidelines, there would have to be some standard method to access the results of a given subguideline. Third, structure would be important to make the output computer-friendly to other informatics applications, such as order-entry systems or prescription refill-printing applications. The "data tree object" from our guideline engine implementation allowed for the ability for recommendations to be inserted in an ordered fashion. Because the inherent structure of the "data tree object" is hierarchical, mapping to and from a "data tree object" and an XML serialization is trivial. The structure used in our implementation is simplistic and was obtained in an ad-hoc fashion; since then, we have begun work on developing a more formal model of guideline output¹¹.

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Guideline Integration Requires an Underlying Common Representational Schema

By: Peter L. Elkin, MD

Statement of the Problem

Interoperability is required to make logical and reasonable decisions regarding inferencing across guidelines. Sharing guidelines can be conceptualized in two distinct ways. First, there is the issue of communicating guidelines from institution to institution. Second, there is the issue of communicating across guidelines when situations arise where individual patients may be candidates for the application of multiple guidelines or portions of those guidelines. Both of these cases require interoperability.

In the first case, it is clear that many institutions have created their own guidelines. These by definition vary in complexity and in the language used to represent the decision points and actions described by the guideline (and perhaps even the conditions to which the guideline is intended to be applied). In the second case one needs to identify the common nodes across guidelines, which can be used as bridges to other guidelines which may apply to certain patient conditions. For example, a guideline for the treatment of "Congestive Heart Failure" (chf) might very well recommend the institution of a Beta Blocker. However, the patient may develop symptomatic bradycardia from the medication and the former guideline could link to a guideline for the treatment of symptomatic bradydysrhythmias. In another example, the same patient might be advised by the protocol to be placed on Digoxin, but the protocol notes that this is risky if the patient is hypokalemic, the chf guideline might link to another guideline, which addresses the treatment of hypokalemia. Links such as these are based on the availability of a robust underlying common representational schema.

Over the last several years there has been considerable advancement within the field of controlled health vocabularies. Large-scale terminologies have been developed which have formal as well as systematic definitions associated with them. These formalisms are the only tractable answer to several problems that have long plagued the Informatics community.

First, we need to be able to recognize redundancy in these large-scale terminological efforts (often they contain hundreds of thousands of terms). When dealing with compositional terminologies (which represent the set of the most robust and flexible representational schemes), one must be able to normalize the terminology in order to accomplish the task of eliminating or preventing unrecognized redundancy. Normalization is the process, which anneals duplicate compositional expressions that have the same meaning. For example, if the term "Cellulitis" can also be expressed as a compositional expression containing "Inflammation" with Topology "Skin" with Etiology "Infectious Disease" then the terminological system, if normalized, would recognize this identity.

Second, we need to have consistent identification of appropriate subsumptive relationships within terminological hierarchies. This is insured by complete description logic based terminologies, as these relationships are generated algorithmically from the description logic itself.

Third, we need to be able to map between different representational systems as "one size does **not** fit all." Here we begin to see the utility of these terminological systems as a tool for accomplishing interoperability between guidelines and their implementation. Each of the rubrics used within guidelines produced anywhere in the world could be made interoperable by mapping them to a common underlying representational scheme. This ability is the cornerstone of the terminological support needed for guideline integration.

Proposed Solution

Indexing each of the guidelines which one wishes to integrate will provide a mechanism for interoperability. This includes national guidelines needing integration with local or regional guidelines (intra-guideline integration) and integration between guidelines (inter-guideline integration). This facility can and should serve as the portal through which one can visualize the similarities between and among guidelines.

I believe that this in and of itself will be useful in gaining local and regional acceptance of national guidelines. This is predicated on the notion that one of the principle barriers to guideline acceptance is the difference in common parlance which exists across our great land. This can be tolerated and indeed encouraged by considering these differences as colloquial terminologies that can be mapped neatly to a consistent underlying reference terminology.

Today's current guidelines themselves are a simplification of the problem of consistent patient management. Today's robust controlled terminologies are still a form of aggregation and cannot and do not attempt to code all aspects of patient care. That said, there is a considerable expressivity in the compositional terminologies, which exist today, and this, in my opinion, is a small price to pay for the interoperability we seek for tasks such as guideline integration.

A common underlying representational schema is essential for the interoperability necessary to successfully integrate guidelines. I believe that this requires a robust underlying terminological system, which is based on a formal definitional schema. I believe that such a mechanism can facilitate guidelines by several mechanisms. First, these mappings can serve as a portal between guidelines regarding the same topic. Second they can serve as a portal between distinct but clinically related guidelines. Third they can be a bridge to reference information to justify the advice given in the guideline. Fourth these mappings can serve as a mechanism to facilitate diversity in representational form without sacrificing clarity of meaning. For these reasons and many others, which for sake of space limitations were omitted, I submit that the underlying mechanism for the interoperability needed to accomplish the goal of guideline integration rests squarely on the shoulder of today's and future controlled health vocabularies.

Representations for sharable guidelines: convergence or diversity?

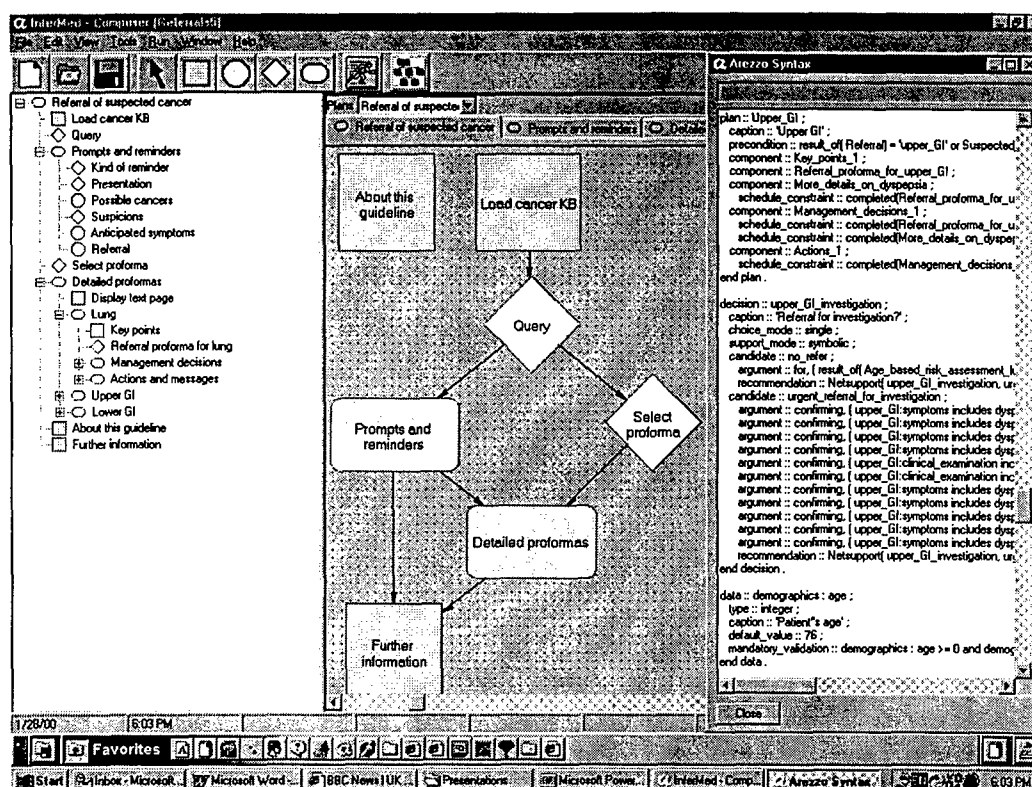
John Fox and Jonathan Bury
ICRF, London, 28/1/2000

As the participants in this workshop will be aware the current massive interest in the creation and use of clinical practice guidelines is something of a mixed blessing. The recognition by healthcare professionals that much variability in quality of care is avoidable, and that it can be addressed in part by the use of guidelines, are significant advances of course. On the other hand the value of the countless text/HTML documents on the web which purport to represent "best practice" is undermined by variability in their quality, in both presentation and content.

As we try to develop executable or *enactable* guidelines, which must be expressed in a technical language such as the Arden Syntax, GLIF or PROforma, formal design and rigorous development become even more critical. A guideline interchange format, like any other computer language, must provide clear standards; agreed terms for representing medical concepts and an unambiguous notation for representing clinical procedures, for example. If we are to achieve sharability of enactable guidelines, particularly if we seek reusability, interoperability etc. then even stricter disciplines must be observed.

The need to address this problem was first recognised in the MLM model of the Arden Syntax. Although experience with Arden has not lived up to all the designers' hopes the benefits of the standards it introduced were considerable and it has been widely adopted. The reasons that Arden did not achieve all its objectives seem similar to the reasons that classical programming paradigm ran into trouble 20 years ago; they did not "scale up". In due course they were supplanted by modern software engineering paradigms like object-oriented programming and the use of CASE tools to support development throughout the development life-cycle.

In the last few years we have seen a similar trend in the domain of enactable guidelines. There have been a number of promising proposals for guideline-oriented representation languages, interchange formats, protocol execution engines etc. Most of these follow a paradigm that has several distinctive features. Roughly speaking this paradigm emphasises *task-oriented* representations (rather than rule-based reasoning or procedural code), *declarative* description formats (which facilitate automatic checking and verification better than traditional procedural languages), *component-based development* (for reusability and reliability) and *lifecycle-based CASE tools* to support quality development and maintenance (e.g. graphical authoring tools). Examples of guideline technologies that embody part or all of this paradigm are Shahar's ASBRU; Musen and colleagues' EON/Protégé; InterMed's GLIF and PROforma (see figure). These technical similarities are not emerging by mere coincidence but because they embody techniques that have been widely and successfully used in conventional software engineering, and more recently in knowledge engineering.



View of a guideline authoring system for the PROforma interchange format (one of the Arezzo® suite of CASE tools developed with InferMed Ltd.) The central drawing area allows an application developer to lay out the task structure of the guideline, here a National Health Service cancer referral guideline, using standard task models for decisions, care plans, actions and data enquiries represented as simple shapes. The thumbnail view on the left shows a hierarchical view of the guideline, which is recursively defined over subplans, and the panel on the right shows the declarative task specification in the PROforma interchange format.

An important side-effect of this growing paradigm is that it creates an opportunity for different research groups to converge technically and this should promote sharability - of ontologies, guideline components etc. In the case of PROforma and GLIF, for example, there appear to be significant similarities between some of the task models used in the two languages. It may in fact be possible to ensure that for certain classes of guideline the PROforma definition could be automatically translated into GLIF, and vice versa, which would permit applications developed for one enactment engine to be reused in the other. We might even agree a standard syntax and operational semantics for the common task types.

Extrapolating from this observation, one might argue that the goal of the continuing collaborations between members of the "guidelines community" is to converge totally, and so we should agree a single standard language. Eventually this will be possible and desirable but we anticipate that most members of the community will feel that this would be premature now. At this point in the development of guideline technology we do not know enough about the technical, clinical or human-interface problems in our area, let alone the most promising solutions. We should clearly remain alert to convergences where these emerge, and translate them into common standards as and when appropriate, but for now different groups are, and should be, pursuing different approaches.

Representations for Sharable Guidelines : Position statement for the Boston Meeting.

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[For some background see: smi-web.stanford.edu/projects/kmg/guideline_panel/index.html]

Development and dissemination of guidelines. Guideline authors have followed the example of EBM by establishing explicit methodologies for guideline development. So far however little has been done to render explicit the processes of deriving recommendations from evidence, or the ways in which it is expected that guidelines are to be used. Many guideline authors probably envisage their use as a generic educational background resource, rather than for case-by case consultation, and their documents are formulated accordingly. Some guidelines (e.g. those produced by SIGN in Scotland) are explicitly declared not to be intended for direct use in practice but only as a basis for deriving local guidelines where issues of cost-effectiveness and resource availability will be taken into account. The methodology for producing locally adapted guideline is even less well defined than that for the national materials they use as their basis. It would probably be salutary for all concerned if guideline authors were to be more actively involved in the design and implementation of procedures for disseminating and applying their recommendations.

Integration of guidelines into practice. There is clear evidence that guideline implementation can improve practice, especially when delivered through patient-specific prompts. Computer systems linked to an EHR (and to other key services, notably for prescribing and orders/communications) have proved in several settings effective tools for achieving this result. This does not mean that decision support in the consultation is the only effective way to communicate guideline knowledge. Efficient web-based resources for educational and reference consultation of guidelines, evidence and literature, in various hours and locations, are likely to remain equally indispensable to maintaining the quality of healthcare delivery. Standard mark-up for search and browsing is not less important than standard KR for decision support.

Knowledge-representation and functional requirements of a shared guideline format. Several benefits are possible from common approaches and convergence towards standards. *Many to many guideline dissemination.* Guideline authors will benefit from a KR standard which makes their material usable in multiple sites on multiple technology platforms. The benefit increases in the case of guidelines designed for cooperating use by multiple care agents. Vendors and users of clinical informatics platforms have greater incentives for installing guideline implementation capabilities if high quality guideline material is available from several reputable authors in a common format. Their development costs may be reduced if common software components, designed to exploit common knowledge formats, can be used in different clinical systems.

Despite these potential benefits, there is little evidence of a clear trend towards conceptual consensus among interested parties, while there are countervailing signs of intensifying competition between proponents of inferencing and authoring technologies based on rival KR models.

This impasse could be broken by establishing a LINUX-like community sharing development of an open-source inferencing component implementing the semantics of a standard knowledge model. Likely agencies with the influence and authority to broker and lead the adoption of standards are public-sector and public interest guideline dissemination agencies and warehouses (in the UK, such candidate agencies are the National Institute for Clinical Excellence and the National Electronic Library for Health). Such a development would generate expanded business opportunities for added-value products linking guideline-driven inference to EHR platforms, and for creation of advanced knowledge authoring tools.

Progress towards a common model may to some extent be partitioned into a set of sub-problems, such as:

- a) An interface for EHR queries.
- b) A grammar for expressing criteria which are capable of being tested by means of EHR queries.
- c) A grammar for specifying recommended healthcare actions.
- d) An algorithm specification for methods used to compute a result or value, which may form a component of a recommendation (e.g. a drug dosage, a risk stratification score, a diagnostic assessment conclusion).
- e) An object model for expressing the compositional structure of a protocol and the criteria governing the lifecycle of the use of a protocol and its parts.
- f) An interface for connecting a component implementing the semantics of items (b),(c), (d) and (e) and a host clinical information environment.

Consensus on any one of the above topics will begin to yield some of the clinical, business and public-interest benefits identified above.

Several of these issues are interlinked with other areas of current health informatics standards work. Delivery of item (a) depends on standards for EHR architecture. Delivery of item (b) and depends on standards for clinical activity and workflow definition. Items (a), (c) and (e) all imply demands (some of them novel) on the range and expressiveness of clinical terminology schemes.

The standards processes for EHR architecture and terminologies have reached a more mature stage than those for the topics discussed here, so that we can share their methods and build on their existing results, even if the latter are not fully sufficient for our needs. An important development in recent CEN TC251 work relating to the EHR has been the choice of (UML-compliant) model-based, syntax-independent formalisms for fundamental standard definitions. This approach can and should be adopted in the present discussion so that choices between alternative implementation syntaxes (whether declarative or procedural in format) are no longer dictated or demanded by the standardisation process. It should be possible, as with the recent EHR models, to automatically derive an XML DTD from a UML model-based standard definition.

A preliminary solution for item (a) above could probably be constructed on the basis of emerging standards results for EHR architecture, and by similar consensus processes including both technical and clinical testing of candidate standards, with equivalent testing of the integrity of knowledge transfer across different systems. Any draft version of a standard comprising items (a) to (f) inclusive above should be accompanied by a joint initiative to create an open-source, public-domain software inferencing module implementing their combined semantics.

Knowledge-representation and functional requirements of a shared clinical trials protocol format. Informatics for clinical trials pose distinct logistical, business and communications requirements (as is also the case for the many and various clinical contexts in which non-trials protocols are used), but no distinct knowledge representation issues.

Organizational approaches to consensus development and standardization of guideline-sharing formats. (Cf. also the remarks above.) Interest in health informatics for clinical guidelines now far outpaces the evidence base justifying any one approach as the way of the future. Many interesting results exist but these are all limited in respect of either (a) extended exposure to real clinical use (b) complexity of knowledge content supported (c) dependencies on a technology platform and host system (d) proof of use across multiple and varying environments. Over and above software and tool creation, the task of knowledge authoring is a potentially crippling overhead and investment in increasingly sophisticated tools has not yet been shown to reduce the difficulty of the authoring process and the concomitant need for scarce and unavailable levels of authoring skill. Moreover, there is as yet no proof that the healthcare community is capable of mastering the combined organizational and technological challenges of safely maintaining and managing over time large digital corpuses of complex shared knowledge.

For all these reasons, approaches to consensus development and standardisation should proceed cautiously and with deliberation.

Clinical Guidelines Representation:

Incrementally Beyond Arden Syntax

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Context

Although much effort has been expended to create clinical guidelines, use of and compliance with guidelines is felt to be less than ideal. Many people believe that presenting tailored, guideline-based decision support at the point of care using computers will improve compliance. However, some argue that current standards for guideline representation may hinder such implementations and impair knowledge sharing. Arden Syntax is an ANSI standard for such knowledge sharing, but some argue that it does not adequately allow guideline representation. Other efforts (GEODE, EON, GLIF, etc) have been made to provide a knowledge representation formalism for clinical guidelines.

Approach

The HL7 Clinical Decision Support and Arden Syntax Technical Committee discussed the issue during its January, 2000 meeting. The technical committee concurred with the following conclusions.

Summary Points

- 1. Arden Syntax is the only widely accepted standard for clinical knowledge representation.** A number of system vendors (e.g., listed alphabetically: Eclipsys, HBOC, SMS) and some knowledge vendors (e.g., Micromedex) incorporate Arden Syntax in their products. The installation base of Arden is growing. Arden is sponsored by an SDO (HL7) that is thriving and which will persist. Therefore, any future standard should incorporate or use Arden as much as possible. Further, Arden Syntax offers a number of features (e.g., operators for temporal reasoning) that make it appropriate for clinical decision support.
- 2. Clinical guidelines, even complex ones, can be represented in Arden now without further altering the Syntax.** However, some other formalisms (e.g. GLIF) explicitly declare inclusion/exclusion criteria as well as the clinical states and their transitions for an entire guideline (instead of a loosely aggregated collection of MLMs). These constructs could be added to Arden to improve guideline representation.
- 3. Any guideline representation that promotes knowledge sharing will have to address the problem of event definitions, clinical vocabularies and database schemata that differ from site to site.** Arden Syntax currently does not offer a standard way to accomplish these things, but the Reference Information Model of HL7 (RIM) is a robust and growing candidate for a standard data model. Accordingly, involvement of HL7 will be important to this effort.
- 4. To improve shareability, a guideline representation will have to provide a mechanism for communicating tailored messages to personnel.** The Arden Syntax TC is actively working on a standard syntax for this process.
- 5. Some people have criticized Arden Syntax as suffering from the commonly-cited drawback of rule-based expert systems: the inability to regulate the order of rule/MLM execution. However, MLMs can be explicitly chained using CALL statements, thus helping to overcome this issue.**

6. Potential roles for Arden Syntax (neither mutually exclusive nor exhaustive):

- (a) It continues as it is without further alteration to accommodate guidelines. A standard guideline representation (e.g., GLIF) would be translated to Arden MLMs at each site in an automated way. Each MLM might represent a single "step" in a GLIF-encoded guideline. In this formulation, a GLIF or other type of "wrapper" would organize a collection of MLMs into a complete guideline. Allowing such modular guideline components would promote knowledge reuse as well.
- (b) It incorporates guideline constructs (e.g., explicit definition of steps and transitions) and thus serves as a complete alternative to GLIF and other representations.

General Conclusions

Because of the growing use of Arden Syntax and investment in information systems that incorporate it, future efforts to represent guidelines should leverage this experience and use the Syntax as much as possible. Arden Syntax will benefit from incremental change to incorporate guideline constructs. In turn, Arden Syntax could serve as a major component of a future guideline representation formalism.

Topic: Knowledge Representation of Situation-Specific Clinical Practice Guidelines

Submitted by: Ronilda C. Lacson, MD

Clinical practice guidelines (CPGs) are systematically developed statements developed to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.¹ The main goal is to reduce variability in clinical practice while following an algorithm that is evidence-based. Adherence to these guidelines is expected to reduce costs of medical care while improving patient outcomes.²⁻³

The evidence-based medicine work-group published an approach to guideline evaluation⁴. Questions that they suggested users ask include "What are the risks and benefits?", "How do these compare in different people and with different screening strategies?", and "What is the impact of people's values and preferences?".

The three main goal of this statement is to recommend that a novel knowledge representation tool for CPGs should explicitly include the following:

1. Patient preferences and utilities,
2. Mechanism to represent and compare various competing options with regards to patient outcomes, costs, and estimated gain from adherence, and
3. Strength of evidence for each specific recommendation.

Patient Preferences and Utilities

Medical decision-making often incorporates knowledge of the medical domain, results of published research, physicians' experiences and heuristics, patient preferences and quality of life issues. Decision analysis is uniquely important because it represents Quality Adjusted Life Years (QALYs) and utilities for treatment selection. This enables modeling of situation-specific variables in a decision-making process. Therefore, it is possible to apply decision-analytic tools to guideline representation.

Recent models that have influenced the practice of medicine include recommendations for estrogen replacement therapy in women, treatment options for hepatitis C, and use of screening mammography in elderly women.⁵⁻⁷ There has been an effort in the past to use decision tables to convert probabilistic data from decision trees into clinical algorithms.⁸ Rule sets are identified that become specific recommendations in a CPG. In the absence of decision tables, text recommendations or computerized decision support tools are available based on results of these studies.

Comparison of Various Care Options

It is important to address that CPGs may include recommendations that are appropriate for specific situation and patient populations. It is therefore necessary to model the competing options as well as the risks and benefits of each one. Cost-effectiveness studies address these issues.⁶⁻⁷ An analysis of the incremental cost-

effectiveness, gain in quality adjusted life years, and other patient outcomes are important factors to know as well. However, it should be easy to represent choices in a decision-making process and make explicit the reason for a specific recommendation, especially with the powerful tools currently available.

Strength of Evidence

Evidence-based recommendations are better followed in practice than recommendations not based on scientific evidence.⁹ Physicians and other guideline users are interested in the source of evidence and the decision-making process that led to a recommendation. A randomized clinical trial (RCT), for example, that compares alternative treatment strategies is usually rated highly as an evidence source. However, there are not enough RCTs available for medical decision-making and the information usually apply to specific patients in specific situations. The strength of evidence may depend on other published clinical trials (and the strength of their design) or on other methods to combine the results of several studies. The latter method may involve meta-analysis, decision analysis, or a consensus process based on actual evidence.

Summary

Creating a model for explicit representation of the decision-making process in CPGs is the major goal of this position paper. This has not been specified in current CPG models. The actual decisions or recommendations that a CPG provides usually include this decision-making process, albeit implicitly. Thus, it will not be an added burden to the overall guideline development process.

In addition, the explicit model will enable supporting information about CPGs to be stated specifically. The users will have a better understanding of reasons why specific options are better than others. It gives the users more flexibility in following local practices when existing recommendations support these. Furthermore, the flexibility also encourages evidence-based practice because users are forced to justify reasons explicitly for specific choices.

Another asset of this model is the ease in representing changes for updating CPGs. When there are changes in disease prevalence or when new technology becomes available, it would be easier to update information in the model.

Cost-effectiveness analysis can also be useful in the current practice of medicine. This is important when several options are equally preferable, but differ significantly in cost.

The creation of a situation-specific and patient-specific model is needed for medical decision-making. As previously noted, the evidence-based medicine working group supports this approach in evaluating CPGs.⁴ It is certainly closer to how decision-making is performed in real clinical situations. Local adaptation of a "centralized guideline" may be feasible in this context.

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Contraindications and Negative Recommendations

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Clinical practice guidelines have been developed and used for multiple aspects of patient care, including referral, utilization, disease management and preventive care (1). In many of these practice recommendations, it is not uncommon to find situations where an intervention, a referral, or a preventive care approach is contraindicated or strongly not recommended. The main goal of this statement is to emphasize the need for a guideline-authoring tool that can adequately represent and implement "negative" recommendations. Specific areas of concern are noted below.

Health Care Resource Utilization

In the era of cost containment, it is necessary to make decisions about adequate and appropriate use of medical technology. Cost-effectiveness studies are entering the mainstream of clinical and scientific research. Several studies support the utilization of diagnostic exams for specific situations only. For example, getting an electrocardiogram (ECG) for patients less than 30 years of age with no risk factors during routine preoperative evaluation is found to be cost-ineffective (2). Although guidelines specifically do not recommend an ECG to be done in this particular situation, inability to represent this negative recommendation may suggest that this was not a part of the guideline or that the authors failed to address this issue. Either way, the point is missed and a user may decide to get the diagnostic exams anyway. Another important

application of negative recommendations concerns referral and consultation with sub-specialists. To illustrate, a gastroenterology referral (for endoscopy) for patients with dyspepsia may not always be indicated (3). Appropriate recommendations are often specified in guidelines for this purpose. Furthermore, omission of negative recommendations may harm patients in some cases. The American Heart Association specifically enumerates situations when endocarditis prophylaxis is not recommended in their scientific statement (4). Inappropriate use of antibiotics for endocarditis prophylaxis may affect antibiotic susceptibility patterns within specific institutions or potentially cause allergic reactions.

Inappropriate Combinations

In an alerting system, the presence of a potentially harmful drug combination may trigger a warning to the user, often evoked through a medical logic module (5). Current guideline representation formats do not allow inclusion of potentially harmful drug interaction. Furthermore, treatment with an inappropriate drug (or combination of drugs) such as single-drug regimen for the treatment of *H. pylori* can not be adequately expressed (3).

Contraindications

A contraindication is defined as a symptom or condition that makes a particular treatment or procedure inadvisable (6). For example, in the

practice parameter for the management of acute gastroenteritis in children (published by the American Academy of Pediatrics), several drugs were specifically listed as either "not recommended" or "contraindicated" for the treatment of acute diarrhea (7). In fact, as a general rule, they specifically stated that "pharmacological agents should not be used to treat acute diarrhea." This needs to be adequately addressed and represented.

Timed Interventions

Finally, it may also be prudent to indicate time intervals when specific recommendations are applicable. This is another aspect of evidence-based care often specified in cost effectiveness studies. Appropriate intervals for cervical cancer screening using pap smears or the frequency of mammography for breast cancer screening will need to be represented. Inappropriate under-utilization as well as over-utilization of these and other preventive examinations at intervals that are more or less frequent than necessary should prompt a reminder to the user that the action is not supported by the current guideline. The same is true for ordering laboratory tests at intervals more frequent than necessary. This is exemplified by the disutility of more frequent serum monitoring for hyperkalemia in hemodialysis patients on erythropoietin (8).

Limitation

A potential danger with this approach is over-representation of clinical practice guideline recommendations. When a guideline specifies conditions whereby a referral is appropriate, does that imply that every other condition is inappropriate? Furthermore, when data

is lacking to specify recommended intervals for screening or interventions, are expert opinions valid? Conversely, the possibility of being over-cautious exists. How does one determine when a positive recommendation implies that any other approach would not be appropriate? However, I do not think that these are issues to be addressed by a guideline representation tool. These are issues for the guideline authors. What is important for us is the ability to accommodate when guidelines contain negative recommendations that are specifically stated. The authoring tool we develop should be able to represent this.

In summary, I have expounded on the need for representation of "negative" guideline recommendations, an important issue not to be overlooked.

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A Life Cycle Model for Clinical Practice Guidelines

Submitted to: **Towards Representations for Sharable Guidelines Workshop**
March 3-4, 2000; Boston, Massachusetts

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Clinical practice guidelines are a mechanism for translating evidence from scientific research into clinical practice with an intended goal of improving health care outcomes. The process of using guidelines to affect clinical practice is complex and can be more clearly conceptualized if divided into several component steps. Delineation of such discrete steps creates a framework that facilitates the sharing of guideline content and the methodologies that promote guideline use. In addition, since new scientific evidence is continually becoming available, such a framework provides a mechanism by which guidelines can be systematically updated.

A proposed model representing the steps involved in using guidelines in clinical practice is shown in Figure 1. In this model, guidelines are conceptualized as existing in a dynamic multi-step "life cycle." This model is cyclical because guidelines are viewed as undergoing periodic revision to incorporate new knowledge. Six discrete steps are identified which include: creation, dissemination, implementation, utilization, evaluation, and modification. This life-cycle model illustrates how scientific research evidence is incorporated into the development and on-going modification of guidelines. It also portrays the ultimate goal of guideline use, which is to improve health care outcomes.

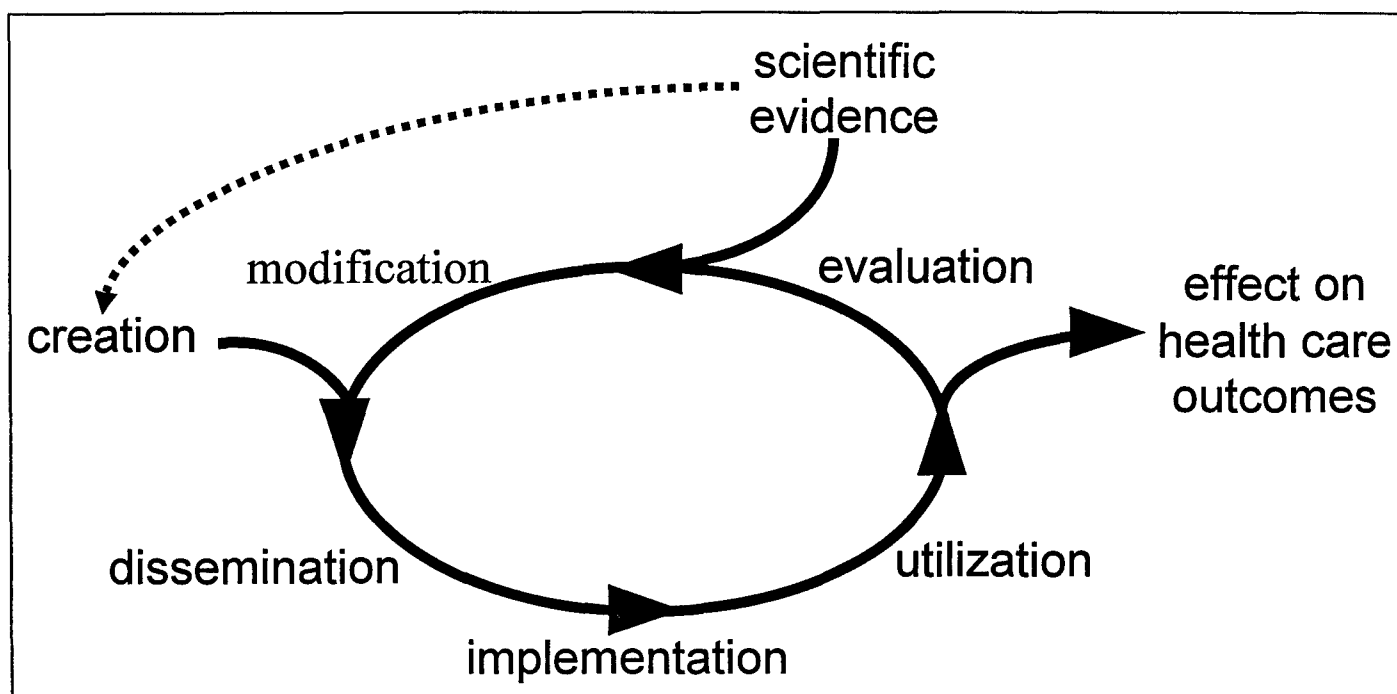
The life cycle model begins with the creation of the guideline. *Creation* denotes the process of identifying and distilling medical knowledge pertaining to a specific clinical scenario into recommendations for its management. The broken line in the model between scientific evidence and creation highlights the importance of sound scientific evidence as the basis for clinical practice guidelines. In the second step, after a guideline is created, it is disseminated to its intended users. *Dissemination* denotes the processes by which a guideline is promulgated throughout the intended user community. Once in the hands of the intended users, the guideline must be implemented into the clinical setting, which is the third step of the life cycle. *Implementation* is the process of making information from the guideline available in a clinical context where this information can influence the care process. Implementation can range from posting a printed copy of a guideline on an examination room wall to elaborate computer-based solutions. After guideline information is available in the clinical setting, it must be utilized. The process of using guideline information to direct health care is step four in this life cycle model and is termed *utilization*.

Although utilization leads to the desired endpoint of influencing health care outcomes, the life cycle model does not end here. It is critical for the guideline to progress through two additional steps. Step 5 in the life cycle is evaluation. *Evaluation*

denotes two processes: first, the evaluation of the outcomes that result from following the guideline recommendations, i.e., do patients really do better as a result of using this guideline; second, the analysis of each step of the guideline life cycle to determine whether or not the methods selected to accomplish the step were effective. Finally, step 6 of the life cycle allows for the guideline to be modified. *Modification* refers to the process of updating or revising a guideline based on new scientific evidence or on what has been learned through the guideline evaluation process. Guideline modification is critical for the long-term viability of the guideline in clinical practice. After modification, it follows that the guideline is re-disseminated, re-implemented and so on to have a continued effect on health care outcomes.

In summary, this model provides a representation of guidelines as dynamic components of the care process that systematically change to incorporate new knowledge. Introduction of this dynamic aspect of guidelines addresses some issues of “cookbook medicine” ascribed to guidelines and the inflexibility often associated with guideline-based practice. This dynamism also leads to a new set of challenges and opportunities in the development and sharing of guidelines for the improvement of health care outcomes.

Figure 1. The Clinical Practice Guideline Life Cycle



Clinical Decision Support: MedicaLogic Position

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1/31/2000

Overview

Medicalogic is committed to providing healthcare professionals with tools to provide them with a broad scope of decision support functionality. Currently we provide them with the ability to:

- Implement practice guidelines.
- Design and generate longitudinal administrative and clinical reports.
- Customize and implement entry forms
- Create protocols that can be triggered by time as well as various types of events, e.g. immunization reminders.
- Create ad hoc querying ability.
- Support point-of-care (preemptive) decision support functionality, e.g. drug allergy and drug-drug interactions.

Logician provides a variety of tools available to those interested in impacting the practice of medicine. Taken together, these tools can provide a powerful armamentarium for effecting change.

Current Components

Encounter Forms

Encounter forms are the primary mechanism by which users document a clinical encounter. Users who create these forms decide what information captured with the form is stored as discrete data and what simply contributes to the note. In addition, form creators can include guideline related static information on disease specific forms to reminder providers. The results of protocols can be easily displayed on forms to impact point-of-care decision-making.

Protocols

Protocols can be implemented within a chart to guide and remind a practitioner of orders that are due for a patient. These are typically driven by dates as well as various other clinical events.

Inquires

Inquiries allow providers to quickly create powerful ad hoc queries within or across charts that would otherwise require many hours of manual labor.

Reports

Design and implementation of reports allow quick and useful aggregation of data across charts for clinical as well as administrative analysis. Stored reports can be generated on a regular basis to assess quality of care, utilization, productivity benefits and reimbursement.

Formularies

MedicaLogic allows users to implement formularies to direct prescribers to more cost effective medications. We provide our users with a Formulary Editor as well as provide a published syntax which allow our users to use third party formulary data (InfoScan) and import directly into Logician.

Open architecture

For the past three years, MedicaLogic has taken the position that clinical content, including protocols, electronic forms, reports, formularies, etc., should be sharable across Logician users. To this end,

MedicaLogic set up the KnowledgeBank (see http://knowledge.medicallogic.com/carbo.dll?icatcommand=knowledge&catalogname=KB_Final) as a forum for our users to share clinical content. This content is created either within Logician or using separate tools available to our users.

Terminology

Medicallogic manages a set of data elements (observations) used by our users to capture discrete clinical data outside of problems, medications, allergies, and orders. Users make requests for new terms and these requests are processed by Medicallogic. In addition, Medicallogic is developing a new unified terminology strategy to support our internet products (Logician Internet and 98point6—consumer health record site) as well as our client-server product, Logician Enterprise. This new terminology model will support all of our new reporting and decision support offerings.

We provide our user with documentation and the relational database schema thereby enabling sites to use third party reporting and analysis tools to answer questions.

Future Directions

Web-based reporting

We have a current initiative geared towards allowing our Logician Internet users to quickly view aggregate data for their practices. In addition, the first phase/implementation provides healthcare professionals with tools that allow them to implement practice guidelines within a single practice or across an enterprise. The professional has access to standard guidelines from well-established professional organizations and the ability to view and customize them to suite his/her practice.

General purpose rules engine

The current protocol engine has limitations. We believe that a general purpose rules engine is required that would allow the identification of triggers (patient checking-in, abnormal lab test returning, etc.) and actions (sending an email, beeping a provider, etc.) as well as a more flexible rules syntax. We have been following the Arden Syntax effort and we are open to exploring the utility of Arden in this context.

Extensions to Web-based reporting

Future enhancements to the web-based reporting initiative will include real time test performance, assessment for a given individual decision based upon population data, local, regional, and national comparisons; best practice assessment and population monitoring.

Common Data Elements for a Clinical Trials Registry

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Section 113 of the Food and Drug Administration (FDA) Modernization Act of 1997 requires the establishment of a public resource of information on clinical trials, whether federally or privately funded, for experimental treatments for serious or life-threatening diseases and conditions [1]. The responsibility for creating the database was given to the National Institutes of Health (NIH) and in September of 1998, Harold Varmus, the former director of NIH, asked the National Library of Medicine (NLM) to take the lead in the project. Given that the scope of the legislation is extremely broad, including not only NIH, but also other federally sponsored trials, as well as privately sponsored trials, we decided to approach the task in phases. The initial phase would involve building the system to include primarily NIH sponsored trials and subsequent phases would incorporate trials from other federal agencies and the private sector. The first phase is coming to an end with the public release of the first version of the system in early February 2000 [2].

The system, called *ClinicalTrials.gov*, currently contains more than 4,000 records and has been designed to provide patients, families, and other members of the public easy Web-based access to information about clinical research studies. Each record in the database includes a summary of the purpose of the trial, together with its recruiting status, the criteria for patient participation, the location of the trial, and specific contact information. Other information in the database that may help a patient decide whether to enroll in a particular trial includes the research study design, the phase of the trial, the disease or condition, and the particular drug or therapy under study. An important feature of the database is that it provides access to other online health resources, such as MEDLINE and MEDLINEplus, that help place clinical trials in the context of patients' overall medical care.

When we began this project it seemed clear that, since data would be coming to us from many different sources, the first step would be to reach agreement on a common set of data elements. In the fall of 1998 we met with representatives from each of the twenty-one institutes who conduct or sponsor clinical trials to discuss a proposed set of data elements. By the end of the year we had agreed on about a dozen required elements and an equal number of optional elements. Our deliberations were informed by earlier work that had been done at NIH, including work on existing disease-specific trials registries, such as the AIDSTRIALS database which was created some ten years ago as a collaboration between NLM, the National Institute of Allergy and Infectious Diseases, and the FDA. Further, we were aware of other efforts in both the informatics and clinical communities on the development of clinical trials systems, e.g., [3-7]. Our current set of

required data elements includes a unique study identifier, a title, summary, recruitment status, eligibility criteria, study type and design, and location and contact information. Optional data elements include references for ongoing or completed trials, results, keywords, and supplementary information, such as related URL's. (For example, if the trial is about diabetes, a related site might be the National Diabetes Education Program.)

Once we had agreed on the basic set of data elements, we needed to work with each NIH group individually in the implementation of our plans. Our model is that of a centralized database to which XML-tagged data are regularly submitted by multiple data providers. The data are FTP'ed to our site, and then we validate and enhance the data for inclusion in the publicly available system which is updated nightly. Since our initial set of data providers (the 21 institutes) differed in their technical infrastructure, technical expertise, and in some cases only had their trial data in paper form, we needed to devise multiple ways for them to be able to contribute to the project. Some had existing databases that contained clinical trials data and in that case our task was to work with them to ensure that they could generate a report that was consistent with our DTD. Even if a database existed, however, sometimes the semantics of some of the data elements were not consonant with ours, and so we assisted in the evaluation and possible restructuring of portions of their databases. For those who did not have a database, we created a Web-based data entry system that would allow them to enter their data *de novo*. Those data come to an ancillary database here at NLM, where it is stored and managed, but the ultimate content control still resides with the responsible individual at the institute. Some other NIH groups took this project as an opportunity to develop the needed technical infrastructure and are now able to deliver the data to us from their databases.

Perhaps the most important lesson we have learned is that in order to effect a project of this scope, and one that involves such large numbers of individuals, is that even if there is general agreement on standards, the devil is truly in the details. The importance of educating individuals about the value and necessity of standards cannot be over-emphasized, and one must be willing to invest the necessary time and effort to do so and to give them assistance in implementing those standards when they need it.

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Maintaining the Knowledge in Computer-Based Clinical Guidelines: A Challenge for the Future

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A challenge for the future will be to develop strategies and tools to facilitate maintaining complex computer-based clinical guidelines as the underlying knowledge evolves over time. A standardized guideline representation could facilitate the development of tools and strategies that could be shared, at least in part, by many different guidelines.

Childhood Immunization We are exploring these issues in the context of IMM/Serve, a computer-based guideline for childhood immunization. IMM/Serve takes as input a child's immunization history and produces recommendations as to which vaccinations are due and which should be scheduled next (and when). IMM/Serve's knowledge base (KB) is expressed using if-then rules, tabular parameters, and procedural logic. IMM/Serve is being used operationally in roughly 10 geographically-dispersed beta sites within the US Indian Health Service (IHS), with planned use at roughly 200 IHS sites nationwide in the near future.

Maintaining a Record of KB Changes We are maintaining a record of all changes made to the IMM/Serve's KB. These changes may be made for several reasons, including 1) changes in the recommendations of national panels, 2) changes in the local interpretation of the national guidelines, 3) local customization, and 4) identification of errors and inadequacies in the logic. Over the past year, there have been significant KB changes for each of these reasons.

Strategies and Tools for Knowledge Maintenance We are developing a suite of strategies for validating IMM/Serve's evolving KB, including tools for automatic generation of test cases using domain-specific approaches (tailored to immunization) and using more generic approaches (which could be used for other clinical guidelines). We are exploring the potential "fit" between the various strategies and tools and the actual KB changes made over the past year.

A Planned Web Site We plan to maintain a Web site which will contain 1) "snapshots" of successive stable versions of IMM/Serve's KB, 2) the corresponding operational versions of IMM/Serve which can be used for research purposes over the Web, and 3) a description of the changes made to each version as described above.

Potential Benefits of a Standardized Guideline Representation A standardized guideline representation could provide several benefits. It would facilitate creation of computer-based tools for knowledge maintenance that could be shared by different guidelines. It could allow the KB "snapshots," and the changes made to each, to be described in a format that would be more accessible to Medical Informatics researchers interested in exploring the nature and implications of such changes.

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Guideline Workshop Position Statement

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Two topics are being investigated at present:

Consensus Development of Guidelines

There are many areas of medicine where evidence based guidelines are difficult to develop. Difficulties in developing guidelines can arise due to the harmful nature of controlled studies and/or the low incidence of a certain problem requiring impossibly large study populations. In these cases, development of consensus-based guidelines is perhaps the next best approach. The web presents a method for the rapid development of consensus based guidelines with an international scope and presumably void of the biases present in smaller efforts (e.g. from professional societies).

We are funded by NIH to develop a method for developing guidelines using an international group of experts and an interactive guidelines web site. The medical topic deals with various forms of neurological monitoring in surgery and critical care. We are investigating the role of expert groups (e.g. entry criteria), moderators for a specific guideline, and user interfaces. The tools being developed are general purpose and can be used in the development of other guidelines. One challenge is to develop the guidelines in a method consistent with the Guideline Interchange Format.

The Bedside Markup Language (BML)

Most clinical personnel agree that it is next to impossible to obtain at the bedside all the information that may be relevant to the management of a particular patient. This information goes beyond guidelines and includes general medical information, drug details, device instructions, policies, etc. The web site of the medical publisher Mosby claims, "According to a recent study, health care personnel have a significant question that goes unanswered for every two to four patients. A bounty of resources exists for health care professionals to answer urgent medical questions. Usually the information is not available where it's needed the most -- at the point of care." One reason for this problem is the variety of formats of bedside information that may be in textbooks, product manuals, policy manuals, videotapes, CD-ROMs, web pages, etc. These various formats almost prevent it from being used quickly at the bedside where it is needed.

In these examples of bedside information, the "content", is coupled to the respective "display and distribution" mechanism. For example, Mosby's GenRx is a drug database (the "content") which you buy as a CD-ROM ("delivery mechanism") for which they have designed a computer-based user interface ("display") for accessing the data. Operating instructions for an IV pump (the "content") may be in a paper manual (the "delivery mechanism").

We have proposed an "uncoupling" of the content from the delivery and display mechanism via the development of a universal bedside information interchange format. Requiring vendors (manufacturers, publishers, hospitals, etc.) to put their "bedside" information in a universal format permits a common user interface at the bedside. The system would allow quick downloads of updated information from a variety of sources.

In this NIH funded project, we are developing a prototype system and exploring a variety of issues including acceptability at the bedside, administrative concerns, and economic issues from the information providers point of view. The project is complementary to the Guidelines Interchange Format in that it makes other information useable at the bedside as well.

DEVELOPMENT AND DISSEMINATION OF GUIDELINES

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The electronic medium is increasingly replacing the usual modes of clinical knowledge transmission and dissemination, namely the peer-reviewed printed journal. Despite the rapid expansion of evidence-based recommendations derived from randomized controlled trials (RCT) and meta-analyses; it still takes approximately 13 years before even half of these recommendations are incorporated into medical practice.¹ To what extent this delay is a function of knowledge overload or difficulty of translating research results into practice-based application is an open question. Yet there is an exception to this knowledge gap; information available at the point of service is likely to be utilized and to positively affect the quality of patient care.

Electronic clinical practice guidelines may be the perfect tool for point of service implementation. These electronic guidelines may be able to overcome the lengthy delay between guideline development and implementation. To achieve the goal of rapid guideline dissemination, guidelines have to be clad in a "standard" and generic electronic format, which allows local adaptation and adoption. In essence then, the success of electronic guidelines is measured in the same way as text guidelines, namely through adaptation and adoption at the local or institution specific level.

To facilitate the guideline translation process from text to electronic format, guideline authors and methodologists, and computer scientists have to share a basic understanding of their respective fields to facilitate a smooth translation from text to

¹ Antam, Lau, Kupelnick et al. 1992. A comparison of results of meta-analysis of randomized controlled trials and recommendations of clinical experts. JAMA 268:240-248.

electronic representation. In effect, the constraints of computer language should not hinder the verbal rendering of guideline recommendations and vice versa.

To begin the dialogue between computer expert and guideline developer, I propose to familiarize the electronic experts with some of the basic building blocks that go into guideline development. I plan to draw on the Institute of Medicine's (IOM) seminal work on guidelines.² In particular, I shall present the IOM attributes of valid guidelines. Since the American College of Physicians-American Society of Internal Medicine's (ACP-ASIM) guideline development program incorporates these attributes, a description of the Clinical Efficacy Assessment Program (CEAP) will follow.

Since an interactive question and answer format is more conducive to learning than a didactic presentation, I plan to minimize the "lecture" part, to encourage open discussion and interaction. A moderator (Steven Lascher, DVM, MPH) will keep the discussion focused.

I welcome your suggestions and comments.

² Institute of Medicine. 1992. Guidelines for Clinical Practice. From Development to Use. Eds. MJ Field and KN Lohr. Washington, DC. National Academy Press.

Propositional Representation of Clinical Practice Guidelines

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Clinical practice guidelines (CPGs) are aimed at physicians of various degrees of knowledge and experience. The expected result of the use of guidelines is the standardization and homogenization of clinical practice (i.e., that the same clinical problem be diagnosed, treated, or managed similarly by different physicians). However, CPGs can be semantically very complex. In fact, many CPGs are composed of elaborate collections of prescribed procedures, sometimes involving the embedding of procedures within procedures or complicated temporal or causal relations among the various steps in a procedure. Furthermore, interpretation of CPGs involves the generation of inferences that are needed for correctly implementing the procedure prescribed by the guideline. The fact that interpretation requires making inferences makes CPGs highly ambiguous and therefore prone to different interpretations by different physicians. To overcome the inherent ambiguity of CPGs, physicians make use of their domain-specific knowledge as well as their general world knowledge. This knowledge helps disambiguate procedural steps and temporal or causal relations among steps. Unfortunately, it is also the source of the differences in CPG interpretation that the CPGs are intended to equalize.

In this position paper, we argue that propositional analysis is an important tool in the development of CPGs. Propositional analysis is a formal method for representing textual information in Cognitive Science [1]. It allows the identification of those aspects of the guideline that, because of their semantic complexity (i.e., those involving generation of inferences), may pose a problem of interpretation for the physician. To this end, it may be an important tool for the development of effective CPGs, when used in the design process. Its utilization as an alternative, empirically-based form of representation can be used at various points in the design process (e.g., development of algorithms, implementations in electronic medical records) as an aid to the development of the content as well as the form of guidelines.

Propositional analysis is a method for the empirical investigation of the semantic structure of discourse, as in a collection of think-aloud protocols from designers and end-users alike. The basic unit of analysis is the proposition. A proposition is an idea underlying a piece of text (e.g., phrase, sentence, paragraph, etc.) and corresponds to the basic unit of the mental representation of symbolic information in human memory. A proposition is composed of two concepts and a relation between the concepts. For instance, the sentence "John went into the house" expresses one proposition that can be analyzed into the concepts of "John", "house", and the relation "went." Propositional analysis, however, does not end with the identification of the concepts and relations. It also involves the categorization of the concepts and relations in the text. In the example above, "John" is the agent of the action and "house" is a location. A propositional representation of the sentence would look like this:

1.1 Go AGT: John, LOC:house, TNS:PAST;

where the number 1.1 in the first column represents the proposition number, the second column, "Go," is the head element or *argument*, and the third column is called the *predicate* (what is said or predicated on the argument). Notice that the propositional representation is always in present (use of "go" instead of "went") while tense information is given in the predicate.

Propositional analysis allows us to identify three types of propositions that indicate the level of complexity of the text: *single*, *embedding*, and *linking* propositions. *Single* propositions express single ideas. These propositions are self-contained; that is, they do not contain or refer to other propositions. *Embedding* propositions contain one or more propositions within them. Finally, *Linking* propositions connect other propositions and represent likely inferences. That is their predicates include one or more proposition numbers. We argue that the presence of embedding and linking propositions indicates the greater complexity of the text. This means that as the number of embedding and linking propositions increases so does the number of inferences needed to interpret the text. Since inferences introduce variability in interpretation, a text with many of these types of propositions will be more variable in its interpretation than a text with fewer of them.

How can propositional analysis aid in the development and utilization of guidelines? Given that CPGs may require a large number of inferences for its proper interpretation, the identification of embedding and linking propositions may be beneficial for the development of more explicit guidelines. These inferences provide coherence to the representation and may be crucial in the proper understanding of the guideline. However, when trying to represent clinical guidelines in automated systems (e.g., Web-based, DSS), the resulting user representation may fail to include information that is shown in the linking or embedding propositions. The complexity of CPGs can however be lessened by converting complex propositions to sets of single propositions easing the need for generating inferences that make guideline interpretation more variable. To tune the information to different levels of user expertise, it may be possible to make this information optional for browsing in the CPG, e.g., by means of pointers. In this way, the expert physician may skip through this information (and therefore make the necessary inferences himself or herself) whereas the inexperienced physician may inspect the information at will.

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Use of Clinical Practice Guidelines: Lessons from Research at the Point of Care

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Each day physicians must make informed, accurate decisions on patient care. This is a formidable challenge considering that the body of medical knowledge is in a state of constant growth and revision. Clinical practice guidelines (CPGs) give a means to manage this 'information overload' and provide up-to-date, scientifically valid medical information to aid the practitioner in making more efficient and effective clinical decisions. The end result would be an improvement in the quality and efficiency of health care. Although the outlook for the potential impact of CPGs is positive, reviews and studies of practice patterns report that practitioners do not make use of this support tool on a regular basis. This noncompliance by practitioners is puzzling because CPGs are meant to help enhance physician performance. So why is there a breakdown? Understanding this process in human behavior can guide us making recommendations for improvement. This position paper argues about the importance of conducting cognitive examinations of the use of CPGs at the "point of care" in order to insure their effective utilization. We present here some lessons for the development of CPGs derived from empirical studies of guideline utilization at the point of care and how the findings can help in understanding successes and failures of guideline utilization by end-users.

We start by presenting some fundamental characteristics of the way experts and non-experts interpret and use information for making decisions [1]. Research has shown that medical practitioners rely on the heuristic of *explanatory sufficiency*, where they generate an explanation for a patient problem just until they are satisfied that the explanation is not too far off the mark. That is, physicians generate only satisfactorily accurate explanations, not maximally accurate explanations. Since this is a function of the level of expertise of the physician, the explanations provided also vary as a function of expertise, which introduces variability in guideline interpretation and decision making.

This difference in explanatory sufficiency is supported by a body of research showing how constructed representations from symbolic material vary as a function of the expertise of the user, the purpose, and the nature of the material to be interpreted. These research results, summarized below, can provide important insights into the design and development of guidelines for use at the point of care:

1. Experts are more likely to make errors of omission, given the high level of abstraction they employ to process clinical information. Therefore, for experts, guideline information can serve as reminders that recall relevant information. For the non-expert, the situation is different. Given their lack of specialized knowledge, they are more likely make error of commission (e.g., ordering unnecessary tests). Although reminders are also useful, CPGs help them focus on the relevant information and discard irrelevant associations.

2. Different purposes require different guidelines. CPGs for problem solving and decision making need to be presented in an easily accessible, and ideally, "just-in-time" form that can be used as part of the problem solving or decision making process. Guidelines for learning should encourage reflection and understanding the deeper meaning of clinical situations and the reasons for undertaking procedures. Such guidelines can provide ways to double-check on decisions taken and thus to prevent errors.
3. Different users may benefit from guidelines in different formats (algorithms, flowcharts, written text). Guidelines in diagrammatic form such as algorithms are useful for problem solving, provided that the user possesses extensive knowledge of the guideline domain, as they provide easy access to the relevant information. Algorithms convey only the major steps in a procedure while leaving room for physicians to adapt the guideline to particular patients, presenting all the important information about a problem at a glance. In written CPGs, the relevant information is dispersed through the text. However, these advantages differ depending on the level of expertise of the user. By combining different forms of guideline representation a more effective use of CPGs can be fostered.
4. Finally, CPGs should allow for idiosyncrasies of individual patients. This can be done by supporting expert heuristics that have been shown to be effective in patient management and by introducing considerations regarding the patient's knowledge and beliefs of health and illness. This requires having a model of the patient as part of the decision support and the guideline, an issue that we are currently exploring.

In summary, the study of the use of CPGs at the point of care is important because it provide insights into how the nature and purpose of guidelines can be tuned to different users, when such research is used in the design process. Thus, we argue that this empirical research, coupled with design principles from the cognitive and behavioral sciences, should be part of the information necessary for the design and development of any form of clinical guidelines.

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Usability Analysis of Guideline Encoding and Application in Clinical Practice

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With the advent of emerging information technologies in health care, including computerized patient record (CPR) systems and the WWW, possibilities exist for exposing increasing numbers of physicians to clinical guidelines. Advanced computer tools have been developed for aiding in the generation and deployment of guidelines in electronic form and promise to facilitate the process of providing guidelines for use at the point of care. However, a number of fundamental questions remain as to how these guidelines can be best be deployed, how they will actually be used in clinical practice, their effectiveness, and how their generation and dissemination can be enhanced using advanced computer technology.

In this position paper it is argued that it is useful to apply methods modified from usability engineering, called cognitive engineering to empirically study the use of electronic guidelines, as they are being developed. Data collected from such studies could be used to identify problems in guideline use and increase the likelihood that the information they provide will be useful. A number of methods have emerged in recent years which have proven to be powerful techniques for analyzing end user interactions with information systems as well as their informational content (Nielson, 1993). These approaches can be combined with methods from cognitive science, which focus on characterizing the cognitive processes involved in carrying out complex tasks, such as interacting with a computer system. Usability analysis aims to assess the efficiency and effectiveness of information systems as they are used for applications by representative users, for example, the use of on-line guidelines by physicians as they carry out clinical tasks. These methods typically involve collecting in-depth process data on use of systems, including audio recording of users interacting with systems or dialogue between physicians and patients. In addition, this can be supplemented with collection and analysis of video recordings of the actual computer screens as physicians interact with information technologies. The information obtained from such study can provide valuable feedback into the iterative re-design, refinement and improvement of information systems and their content.

Guidelines are becoming increasingly available on-line and physicians are now able to access guidelines while using a CPR system, for example, by browsing through the system and selecting to access guidelines relevant to a particular patient encounter. We have initiated work in remotely tracking the use of guidelines as physicians use a Web-based CPR system. In addition, the technology is in place for remotely collecting video recordings of user interactions with on-line guidelines. To date we have collected usability data over the WWW consisting of records of user interactions with ACPOnline. This has involved presentation of on-line forms for querying physician users at point of care as to why they are accessing the guidelines and upon exiting the guideline to obtain an assessment of how useful the information was. Our preliminary results indicate that physicians use guidelines primarily for upgrading their general knowledge (typically while patients are not present).

It will be essential to extend such analyses assessing usability of guidelines in order to obtain critical information on how to best bring evidence to bear in a manner which is "just in

time", and appropriate for application in real clinical contexts. Along these lines, the following will be required:

1. Detailed assessment of how clinical guidelines are actually used at point of care, using methods described above, as well as study in a variety of work contexts.
2. Identification of problems or barriers that reduce the effectiveness or applicability of guidelines, based on empirical data from actual use.
3. Assessment of the relationship between computer-based patient record (CPR) technology and possibilities for making evidence more accessible to physicians.
4. Recommendations for improvement in the uptake of evidence using guidelines, based on results from in-depth usability studies.

In addition, it is argued that the processes involved in encoding guidelines must also be empirically studied, since the encoding step forms the basis for the information that will be ultimately presented to end users online. This should involve collection of process data (e.g. video and audio recordings) from subjects interacting with software for encoding guidelines. Through our preliminary work in this area, we have been able to characterize the steps taken in modeling guidelines using the GLIF representation language and identify potential difficulties encountered in the task of encoding guidelines – difficulties encountered both with the underlying guideline and with the computer-based representation in performing this complex task. This approach has led to identification of both generic aspects of the process of guideline encoding (e.g. complexities in decision making involved in translation of guideline steps into a computer algorithm) as well as specific problems in performing this task (e.g. difficulties with the user interface). It has been documented that problems related to user interactions with systems identified from study of few representative users are typically generalizable to much larger user populations, making usability engineering methods cost effective for providing iterative input into improving user interactions and informational content [1]. These types of analyses could be extended to the study of encoding of a variety of guidelines.

The information resulting from in-depth usability analyses can be fed back into the design of information contained in the guidelines and the fine-tuning of the underlying representational schemes used to encode guidelines. This formative input should lead to improvement in implementation of guidelines and ultimately improve their effectiveness as they become deployed in various electronic forms.

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The role of ontologies for an effective and unambiguous dissemination of guidelines.

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Guidelines for clinical practice are being introduced in an extensive way in more and more different fields of medicine. They have the goal of indicating the most appropriate decisional and procedural behavior, optimizing health outcomes, costs and clinical decisions.

Guidelines can be expressed in a textual way as recommendations or in a more formal and rigid way as protocols or flow diagrams. In different contexts they can be either a loose indication for a preferred set of choices or they can be considered a normative set of rules.

Clinical practice guidelines are seen as a tool for improving the quality and cost-efficiency of care in an increasingly complex health care delivery environment.

Computerization may increase the effectiveness of both the information retrieval of guidelines and the delivery of guideline-based care. In an optimal scenario they are integrated with the information systems operational at the point of care. The full potentialities of computerized systems can be exploited in such an environment where different processes are executed in parallel on several patients. In this context such systems must be able to retrieve the updated situation of every patient, as well as to give an overall report on the ward, freeing the physicians to concentrate more on clinical decisions. Keeping track of the parallel activities performed, they should avoid unnecessary duplication of tasks and prevent possible omissions.

The scenario is evolving from stand-alone workstations to telematics applications that - utilizing e.g. the Internet (see for example <http://saussure.irmkant.rm.cnr.it/guidelines> for a collection of resources) - not only support the use of guidelines, but also enable their development and dissemination. However, the ever-increasing demand of guidelines dissemination has to rely on a solid conceptual foundation in order to give a precise semantics to the knowledge shared. Such a knowledge sharing requires the definition of formal models for guidelines representation. The models should have a clear semantics in order to avoid ambiguities.

The role of ontologies is that of making explicit the conceptualizations behind a model. In particular an ontology contains the formal description of the entities to which a model makes a commitment and of the relations holding among the entities. In our perspective, an ontology is a formal theory which partially specifies the conceptualization (i.e. the intended meaning) of the terms used to talk about the entities in a domain.

The realization of ontologies is the groundwork for making a standard model acceptable and sharable. An ontology library is not normative, but allows an inter-subjective, explicit and formal agreement on the semantics of the primitives of a model, by referring to more generic primitives (generic theories).

We defined an ontology of guidelines which is part of a larger ontology library containing both domain and generic theories. We believe that such an approach can facilitate the standardization process by allowing an explicit mapping in a formal ontology of the concepts represented in the heterogeneous models proposed so far.

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Integrating Guidelines into the HL7 Reference Information Model

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HL7 is the primary interchange standard for clinical data, both in the U.S. and internationally. Clinical data sent with HL7 includes numerical, coded and text data for the Electronic Medical Record (EMR.) Besides the exchange of actual patient data, HL7 2.x also covers ordering and scheduling of clinical work, as well as exchange of data dictionary (master file) records describing clinical parameters. HL7 2.x order messages are being used to communicate workflow processes as well as care plans. However, the current version 2.x of HL7 representation of care plans is difficult because of ambiguities, semantics hidden in syntax, flat structure, unsystematic specification and implementation, and because of the vocabulary problem.

Currently HL7 is being redesigned in its version 3 effort, which includes the creation of a comprehensive Reference Information Model (RIM) [1]. The RIM covers all entities and data elements about which HL7 messages communicate. The HL7 RIM went through multiple revisions to evolve from a very specific reverse engineered representation of HL7 version 2 message content to a generalized model describing most of the information structures of clinical care. In its latest revision, the clinical areas in the RIM have changed significantly, to implement the Unified Service Action Model Proposal (USAMP) submitted jointly by the HL7 Committees Orders/Observations and Patient Care [2] (see appended Figure 1.)

The USAMP restructured the RIM around a few clearly emphasized key-concepts. Firstly, we generalized all clinical events under the notion of the service action. This means, no clinical data exists outside of a service action object. Secondly, we allow arbitrarily complex clinical expressions using a typed Service-relationship as a link between two services. Finally, we defined the concept of action mood, to clearly distinguish the various ways an action can be conceived, i.e. as action definitions, action plan instances, and results of actions (e.g., observation results.)

We borrowed the term *action mood* from natural language grammar (lat. *modus verbi*). The notion of action mood also resembles the various extensions of the logic of facts in modal logic. In USAM, an action is represented as a

predicate $A(m, x_1, x_2, \dots, x_n)$ where the mood m specifies the modality (fact, possibility, intention, goal, etc.) under which the truth of the predicate is determined. The other arguments x_1, x_2, \dots, x_n describe actors, subject (patient), timing, observation value etc.

The service relationship is a relation sRt where R is the relationship type, s the source action and t the target action. Service action relationships are usually asymmetric and transitive. Service relationships come from a few categories: generalization, participation, precondition, postcondition, and revision. Generalization allows defining classical subtypes. The participation defines sets or ordered collections of services, e.g., the steps of an action plan are sub-services contained in a super-service. Preconditions are the conditionals that allow, suggest, or prevent an action from being executed. Postconditions are the used to express goals (intentions) and maintenance or end conditions of actions. Revision is used to link action plan instances to their definition, revised action plans to the original plans, and action events to action plans.

Because actions in all moods are described through the same information structure, we had to define all the data elements describing an action so that they would be sensible in all moods. This is possible if we conceive all action values as sets that are successively constrained across the different action moods. For example, the time of an action in *definition* mood is the set of all possible time periods in which the action can occur (e.g., business hours.) The time of an action *intent* is constrained to a smaller set of preferred times. Finally, the action *event* happens at a specific time. That all attributes of an action are successively constrained sets also explains why some observation values are ranges (e.g., blood glucose < 20 mg/dl) while most appear to be points (110 mg/dl.) All measurements are but constraints of the actual value inside a confidence interval. The USAM model corresponds well with constraints approach to decision support as found in constraint logic programming (CLP) and related work.

In the USAM, we attempted to systematize the ways HL7 messages communicate the requested workflow and completion of the work. By means of the mood code, we can take the structure that specifies an action plan ordered for a patient (HL7's primary concern) and reuse it to describe general action plans, known as care paths or guidelines.

Likewise, the USAM's reuse of one action structure in different mood guarantees that any clinical data that is reported can also be used in guidelines as conditional criteria or goals. Since most clinical data are reportable through HL7, we can directly use this data in guidelines. This overcomes the impedance mismatch between guideline systems and the medical record that is evident in the Arden's "curly braces problem" and in the unspecified conditional expressions in GLIF.

We found many similarities between the USAM and other guideline work, notably the notion of skeletal plans in ASBRU [3], and the model based approach to guidelines defined in EON [4] and GLIF [5]. The USAM group now seeks to cooperate with the HL7 Clinical Decision Support TC (ARDEN) and the INTERMED group to refine our model-based approach to guidelines.

We believe that such a cooperation could be of benefit to all parties involved. The HL7 guideline features could grow through the Expertise in the INTERMED project to a robust technology that is actually tested and used in current and new guideline systems. On the other hand, the INTERMED project could benefit from being embedded into

HL7's linkage to the medical record, and its ability to move standard messages into public use. Together we could make truly interoperable guideline exchange work.

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GEM: A Guideline Document Model Using XML

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Objective: Our long-term goal is to apply the knowledge contained in practice guidelines to support clinical decision-making. As a requisite step toward that goal, we have designed a model using XML to simplify and standardize encoding of the content of guideline documents. The model includes a sufficiently broad set of concepts to be useful throughout the guideline lifecycle.

Design: Current guideline document models are limited in that they often reflect only the specific orientation of their designers. Thus, developers and disseminators provide few constructs in their models for conceptualizing guideline recommendations, while implementers de-emphasize concepts that are necessary to establish a guideline's validity. We developed the Guideline Elements Model (GEM) using XML to represent the heterogeneous knowledge contained in practice guidelines. Core constructs were derived from the Institute of Medicine's Guideline Appraisal Instrument, the National Guidelines Clearinghouse, the augmented decision table guideline representation, and the Guidelines Interchange Format (GLIF). These were supplemented with additional concepts derived from a literature review.

Results: The GEM hierarchy includes more than 100 elements. Major concepts relate to a guideline's Identity, Developer, Purpose, Intended Audience, Method of Development, Testing, Review Plan, and Knowledge Components. Knowledge Components, in turn, include Recommendations (which comprise Conditionals and Imperatives), Eligibility Criteria, Definitions, and Algorithms. The GEM Document Type Definition and Schema can be used to validate guideline documents represented as GEM files. We have marked up several guidelines from a variety of sources to establish the comprehensiveness of the GEM ontology.

Conclusion: GEM is expressively adequate to represent the heterogeneous information contained in guidelines. Use of XML contributes to a flexible, comprehensible, sharable, and reusable knowledge representation that is both human-readable and computable.

Current Activities: We are creating tools to assist with guideline markup and automated implementation of guideline recommendations. The proposed model is being evaluated in informatics laboratories at 2 other institutions to investigate differences in the organization of medical concepts when GEM is used to represent guideline knowledge.

Clinical Practice Guidelines: Principles for Life Cycle Systems Engineering

By

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We envision a world with tens of 1,000s of guideline rules (it took us 1,000 rules just to make the CDC's vaccine guidelines executable) – too many for each organization to re-program. So, of primary importance is the scalability, reliability, adaptability, and portability/seamless integration of large collections of executable guidelines. To support this view, we have been constructing a specification for an open software-based, formal method for engineering of machine-executable practice guidelines into decision support environments. Called Computer Aided Decision Support Engineering (CADSE), it is a top level map of what life cycle engineering should encompass as pertains to clinical practice guidelines, caremaps, trial eligibility rules, and the like.

What is needed is an environment that utilizes software engineering tools, formal methods, and open standards to permit cross-organization authoring and local tailoring of guidelines with appropriate management of versions, copyrights and ownership, and that provides public interfaces that permit any vendor's decision support tools to display the guidelines within their proprietary interfaces. Specifically, we follow the **Embedded Systems Principle**: executable guidelines for decision support, protocols for clinical trials, and so on must interact with clinicians and patients through current vendors' applications (e.g., patient record systems, charting, order entry, clinical trial software, results reporting applications, etc.) – the so-called "legacy" software.

We also envision a distributed set of clinical specialists who wish to create new guidelines and retrieve and adapt them for local practice. At present this community exists as authors, adaptors, and maintainers of 1,000s of non-executable, electronic guideline documents many of which are on the web.

In between the authors and the vendor applications is the role for CADSE, which itself may be thought of as a three-layered block. At the top layer, there needs to be an environment to support the authoring, checking, local adapting and updating, version management, and maintenance of guidelines. **Authoring and Local Adapting Principle**: This environment should collect and display guideline knowledge and other forms of evidence via the help of models of generic tasks in guideline authoring, skeletal plan refinement, terminology-enabled elicitation, visual programming, and wizard assistance and critiquing. Central to this idea are the semantics of not just guideline conditions and steps (current GLIF) but also of higher level artifacts (e.g., temporalities and caremaps, eligibility questionnaires and uncertainties, and treatment tradeoff tables, among many others) that can only be discovered as one begins to construct visual programming widgets that are the intuitive forms in which clinicians think and will seek to actually author, adapt, and update guidelines. CADSE also requires the guideline knowledge to be unambiguously terminology-tagged and to be represented in an open standards, programming language-neutral, canonical form (CADSE middle layer) for which parsers

can readily be deployed to translate it to any vendor's format, although vendors will have to support such interfaces.

Equally vital is for CADSE to provide formal methods for ensuring intra- and inter-guideline reliability. Clinical guidelines are complex objects, and guideline authoring is an error-prone process. Since patient's health, and even life, may be at risk, it is critical that one assures the semantic consistency of guidelines. **Reliability**

Engineering Principle: In general, a guideline (or a set of guidelines) is inconsistent if it can recommend contradictory actions, which should never be taken together, or fails to give a recommendation when one is needed. Process algebra could help us find and eliminate inconsistencies if a few changes are made to GLIF. GLIF guidelines have a fixed declarative structure, that is: 1) conditions and eligibility criteria are clearly separated from actions; 2) information flow through the guideline is fixed and can easily be traced by a computer program. The only difficulty is that GLIF was originally created as a structural semantics based on CORBA's Interface Definition Language or IDL. So for reliability checking formalisms to work, one must have a process (state transition) view of the semantics. One must extend GLIF's semantics for criterion logic based on process and temporal algebra. At present the GLIF has neither primitives for building step (e.g., criteria) statements nor terminology standards, but instead allows free text statements for all steps. This makes it difficult to manage terminology, to verify logical actions, and to handle data and actions. What is needed is to add to the GLIF standard a terminology-enabled conditional logic for representing statements such as criteria, conditionals, If-Then-Else type of sentences, and so on. With these simple extensions added to GLIF, we can apply process-algebraic techniques to guideline analysis.

As mentioned above, the middle layer of CADSE expects the executable guideline to be represented in a language-neutral canonical form. This applies to the semantics not just of the knowledge model, but also of the information and data model implicit in every guideline document and that is vital to the ultimate binding and integration of that guideline with patient data. At present, however, GLIF ignores the information and data model. Terminology tagging of guideline lexicon is an essential step to alleviating this difficulty. However, that is only half the battle since guidelines often require a number of intermediate operations to be performed to patient data before they can use it (e.g., aggregation, averaging of observations, trend analysis, filtering, translation, units conversion, etc., etc.). We call these intermediate operations "knowledge mediation steps". **Knowledge Mediation Principle:** For guidelines to become truly portable, any canonical representation must terminology tag both the knowledge and information models of executable guidelines, and require vendor applications to map their local dialects to the standardized terminology set. Further, it is vital to adopt standards (e.g., Object Query Language and Object Definition Language) and toolsets that allow the rapid authoring, adapting, and sharing of reusable libraries of mediators that support the intermediate operations. At present GLIF ignores both pieces of this principle – the information model and the mediation code.

Finally, the lowest layer of a CADSE makes guideline knowledge a resource and service the vendors' applications obtain from the operating system, much as they obtain other execution level services (e.g., event handling, publish and subscribe brokers, name

servers, encryption, message routing, etc.). Some of these services are germane only to medical applications such as terminology service and master patient index. **Guideline Execution Services Principle**: Still other of these services are peculiar to guidelines alone, such as a virtual guideline machine (execution engine), a mediator generator and wrapper, and a matchmaker -- a broker that polls for the proper guidelines to run. It is vital to create and implement such services, if CADSE is to become a reality.

Consistency of Clinical Guidelines

By

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We address a problem of authoring and maintaining large collections of clinical guidelines. The process of guideline authoring is a difficult and error-prone activity. At the same time, guidelines are safety-critical systems, because health and even life of patients depends on correctness of procedures prescribed by the guidelines. Because of this, it is extremely important to verify guidelines before they are used.

We propose an approach to analyze consistency of guidelines by means of a mathematical formalism known in computer science as *formal methods*. Formal methods are used for analysis of safety-critical systems in avionics, aerospace, telecommunication industries, etc. Formal methods treat a system under consideration as a mathematical object, and provide a proof that the system complies with its requirements. The proposed validation approach will be a part of a larger environment for authoring and maintenance of clinical guidelines called CADSE (Computer Aided Decision Support Engineering) that is being developed at the University of Pennsylvania.

The large amount of data that is involved in guideline analysis makes it a daunting task. Early work on semantic analysis of rule-based systems [1,2] failed to yield practical results. In these systems, analysis was made intractable by very expressive languages used for expressing rules. These languages allow the rules interact in arbitrary ways, making exhaustive analysis of all possible interactions infeasible or even impossible.

If we want to thoroughly analyze thousands of guidelines, we need a more structured language for expressing the guideline rules. An ideal language would, on the one hand, allow guideline authors to express everything they need in a guideline; on the other hand, the language will promote a disciplined way of writing rules, keeping analysis complexity low. The GLIF language [3] has a possibility of being used as such structured language. The advantage of GLIF is that it organizes the rules in the form of a graph, representing decisions made, and actions taken, during the execution of a guideline. This representation provides a clear separation between conditional rules and eligibility criteria from actions recommended by the guideline. In addition, the structure of a graph explicitly represents the order of application of guideline rules. These two provisions make analysis of the guideline much easier.

We consider three types of inconsistencies in guidelines that can be analyzed by means of formal methods:

- *Intra-guideline* consistency analysis deals with inconsistencies within a single guideline. Intra-guideline inconsistencies include structural defects, such as circular paths and dead-end branches; ambiguities, when a guideline may recommend more than one action for the same combination of input data; incomplete coverage, when no action is recommended for a certain input.
- *Inter-guideline* consistency analysis is concerned with detecting interference between guidelines for separate medical conditions. When more than one guideline is applicable to a patient, independently developed guidelines may recommend conflicting actions. For example, drugs that cannot be taken

together may be prescribed by different guidelines. It is important that the possibilities of such interference are detected before the guidelines are deployed.

- *Inter-author* consistency analysis ensures that versions of the same guideline, developed by different authors recommend the same actions under all circumstances. Independent development of a guideline by several authors is often used to avoid oversights of a single author. Comparison of the resulting guidelines is a non-trivial task that is itself prone to errors. A mechanical support for such comparison is an important feature of a guideline authoring system.

In order to fully support analysis of the three types of guideline inconsistencies, semantics of GLIF constructs need to be refined and extended. Currently, conditional expressions and actions are stored as textual attributes of conditional and action nodes, respectively. To carry out the analysis, the language of conditions and actions need to be fixed and its semantics precisely defined.

To summarize, our future work on guideline analysis will be carried out within the CADSE development project, a framework for computer-aided guideline authoring and maintenance. Our two main goals with respect to computerized analysis of guidelines are: 1) provide extensions to GLIF semantics that would enable formal analysis; 2) adapt existing formal methods to the specific needs of guideline analysis.

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Guideline workshop, Boston, march 3-4, 2000

Position statements

Premise - Despite the great emphasis that medical community put on clinical practice guidelines (GLs) during last years, several problems are associated with GLs diffusion and implementation in clinical setting. "Official" GLs, delivered by health care authorities (health agencies, medical associations, health policy makers, etc), may show two opposite faults: if they are very general their interpretation is difficult and ambiguous, while if they are very specific, they may not fit the organisational constraints of the different environments where they must be implemented. In addition, and independently from organisational reasons, health care operators often do not fully comply with GLs, simply because it is difficult to impose behavioural changes. If a local standard already exists, physicians offer resistance to change, and this is reasonable, especially if they do not perceive an advantage. To this concern, it must be recognised that often physicians are not provided with instruments for evaluating the benefits of a GL introduction, thus lacking the opportunity to be convinced by the evidence of improved outcomes. Last but not least, guidelines are often represented as a set of rules, and little emphasis is put on decisions requiring a "utility" assessment.

This premise motivates our current efforts in the field of guideline integration into the clinical practice. In the following our current position is summarized:

- We developed a formalism for computerised GL representation. Different formalisms have been developed by other groups and we agree that efforts must be done in order to create a *common language* for knowledge sharing. We also should promote the use of these tools by the experts developing GLs, because often the prose is ambiguous and the "textual" GL is not complete. On the contrary, a computerised representation requires (or, at least, is able to verify) the GL logical correctness;
- We are working on the "compliance problem". We know that it may be improved by integrating GL with the electronic patient record (EPR); to this concern, it must be stressed that for performing sound statistics on the GL impact it is necessary to verify which tasks have been completed and the motivations for the possible non-compliance; integrating GL with EPR implies tackling the terminology problem as well;
- We think that different inference engines (i.e. mechanisms for advice production, given the specific patient data) must be allowed for the same GL, in order to achieve a user interaction that is tailored to the specific clinical setting. As for any other information tool or decision support system, it is very important that the GL do not

badly interfere with the clinical routine. A user needs analysis, as well as a workflow analysis of the clinical environment must precede the GL implementation.

- The computerised representation must also facilitate the GL evaluation. Following the most recent medical informatics community suggestions, the representation must embed knowledge about the goal of the guideline and, when it is the case, about the goal of particular tasks composing the guideline itself. Goal-related outcomes are then stored in the EPR, in such a way to measure the GL benefit.

We focus the attention on the GL/user interaction, and we distinguished three key interaction aspects that, in general, may be tackled differently, according to the specific user needs.

1. The *advice production*: it can be "explicit", i.e. as long as a task is performed, the GL suggests the next steps. This can be a suitable modality for beginners. On the contrary, it can be "silent", i.e. the user is advised only when a non-compliance is detected. This can be worth for expert users.
2. The *approach to non-compliance*: a GL could proceed to the next task(s) only if the user fully complied with the GL for what concerns the previous tasks. This should be the case for particularly mandatory procedures; another possibility is that the GL proceeds also in case of non-compliance, but only if the user provides a justification for that; finally the GL could proceed in any case, just storing the non-compliance.
3. The *intervention time*: a GL could react in real time to the users actions, and suggest, in real time as well, the next action(s). This implies for the user the possibility of interacting very frequently with the computer and thus a very efficient and distributed information system is necessary; on the contrary, the user could access the GL only in specific time slices.

These three aspects concern the real-world implementation of the GL, but another important issue is the GL use for educational purposes, where the focus is on aspects such as explanations and literature pointers, and where the user simulates patients, by filling a fictitious patient record with clinical findings, and he/she will obtain advises.

From Guidelines to CAREFLOW management system

Which is the technological solution for the above mentioned application problems? Modelling medical knowledge into a guideline allows establishing *what* to do, but it is necessary as well to model organisational knowledge because it allows to establish *how* and *by whom* to do. Our opinion is that a Workflow Management System (WFMS) could be the correct tool to fully implement a GL and to control its outcomes. In fact, a WFMS is defined as "a system that completely defines, manages, and executes workflow processes through execution of software whose order of execution is driven by a computer representation of the workflow process logic". When the medical process model is provided by a GL, we refer to the system as a GL-based WFMS or, alternatively, CAREFLOW. Through such a system, we could be able to answer questions as *Is there any bottleneck in the hospital structure that impairs the GL implementation?*, *How much does it cost to implement the GL ?*, *Is any human or technological resource over- or underloaded?*, and so on.

An important aspect to take into consideration, to save time and resources from the development point of view, is that WFMS are very common in real world settings other than health care. Thus, we tried to exploit results achieved in those contexts, by importing the sharable technology into the health care context. In other words, we propose a methodology for integrating research tools developed in our laboratories with available commercial tools able to manage classical workflow models.

As a bench-test we experimented the implementation of a GL for the stroke management, actually under evaluation in four Italian Stroke Units (the GLADIS Italian group – GuideLine Application for Decision in Ischemic Stroke). This project aims at evaluating the benefit of GLs for the management of a disease that represents the third cause of death in industrial countries, and the first cause of permanent disability. It is then a source of both direct and indirect social costs. Preliminary data on about 400 patients show that the guideline application improves outcomes and decreases costs.

Acknowledgements: Our research on computerised guidelines is partially funded by the European Commission through the project PatMan (Patient Management) within the Health Care Telematics Applications Programme. The authors thank S.K. Andersen and the other partners of the Patman Project for their helpful comments.

Integrating Guidelines in Clinical Practice Using Electronic Medical Records

Paul C. Tang, MD, Charles Y. Young, PhD

Integrating guidelines into the routine workflow of patient care has been a critical obstacle to effective use of any guideline. Most of the clinical reminders generated by systems in operation invoke simple rules (e.g., health maintenance reminders, drug interaction checking, disease-specific treatment recommendations). Guidelines that are more complicated or involve more professional interpretation are often difficult to implement in computer programs because they require precise definitions and complete data. Until executable guidelines tailored to specific patients become available on a routine basis, healthcare professionals will need to access, read, and interpret textual guidelines themselves. Such textual guidelines constitute the preponderance of guidelines currently available. Finding an effective way to implement these guidelines (many of which are available as HTML documents on the Internet or Intranet) would leverage a substantial body of clinical practice knowledge that is currently underused.

We propose a mechanism to integrate textual guidelines at the point of care using electronic medical records systems. Initially, the textual guidelines would be published guidelines as they appear in print or on Internet Web sites. Later, when more sophisticated inferencing methods are employed to apply domain knowledge to specific patient contexts, we propose that the output recommendations also be returned to the EMR as textual documents, which can be processed using the same mechanism used by the static documents.

We propose that an XML document be defined that includes provisions for embedding standardized language that allows an EMR system to process the user-selected actions from the guideline as EMR orders, thereby eliminating any redundant action required to "transcribe" a guideline recommendation into an EMR order. The XML document could be composed of a static document published by a guideline development organization or a dynamically generated set of recommendations derived from a decision support system. Agreement on the format and syntax of the EMR-enabled XML guideline document would be a simple method to ensure compatibility among guideline developers and EMR vendors.

We envision that the next step in guideline integration would be for a guideline server to provide patient-tailored recommendations to the CPR without requiring users to read through the guideline themselves. This would require more sophisticated structure in the guidelines and the ability for the guideline server to perform reasoning. One possible scenario for the interaction between the guideline server and the CPR system could be the following. The CPR would send a message to the guideline server requesting the invocation of a specific guideline. The guideline server would return a query back to the CPR requesting specific information about the patient needed to custom-tailor the recommendations. This request could take the form of an XML document (compliant with HL7 PRA standards) with certain fields presented as blanks (e.g., query by example). The CPR would then fill in the required fields and pass back the XML document containing patient data to the guideline server. The guideline server would process the patient information in the context of the relevant guideline and return a patient-specific recommendation to the CPR for presentation to the user in the form of an XML document.

Appendix C
Summary presentations from breakout groups

GLIF Conference:
Functional Requirements Break-
out Group

Dan Kent & Perry Miller, Recorders

Boston, MA
March 3-4, 2000

Boston, MA
March 3-4, 2000

The Four P's

- ★ Problems to be addressed
 - Prioritize
 - Plan
 - People

- Prioritize
- Plan
- People

Problems to Consider

- Boundaries of GLs
 - what is GL, an API, a translator
- Access to input data
 - mediate data translators (e.g. DOB to age)
- Coupling GL to work flow
- Maintenance
- Handle negative recommendations
- Handle patient preferences

- ## More Problems of Concern
- Handle uncertainties in evidence
 - Tailoring issues, how flexible?
 - Consider costs and quality of operators
 - Unambiguous terminology tags
 - Supports abstractions in constructs
 - Outputs represented as actions

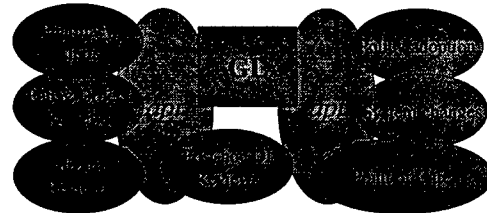
- Handle uncertainties in evidence
- Tailoring issues, how flexible?
- Consider costs and quality of operators
- Unambiguous terminology tags
- Supports abstractions in constructs
- Outputs represented as actions

And Further Concerns

- Verifiability
- Reliability of Replication
- Human Comprehension limits
 - Readability, expressivity controls
- Present clear statements of
 - strength of evidence
 - strength of recommendations
 - magnitude of anticipated benefits

- ## Boundaries for GLs
- What to specify as within GL, versus what makes linkage of GL easier?
-
- The diagram illustrates the boundaries for GLs. A central box labeled 'GL' is connected to six surrounding boxes: 'Language A', 'Language B', 'Language C', 'Language D', 'Language E', and 'Language F'. The connections are labeled 'Linkage'.

- What to specify as within GL, versus what makes linkage of GL easier?



Access to Input Data

- Basic access, data ports or user entry
- Semantic matches
 - blood sugar must equal glucose
 - mg/dL = mM/L conversion?
- Coping strategies for missing data
 - in design versus in real time?
 - Does GL stop, proceed or seek alternate source?

From GL into Clinical Workflow

- mechanism or several to do this are essential
- GL as text, hard to translate into work
- In text, no more than a few ideas and <1 page
 - the greasy plastic laminate placed in each chart
 - one click drill-down is one too many

Maintenance mechanisms

- content & technical maintenance
- update management
 - timely, accurate
 - responsive to recalls
- interactive with local adaptations
- Technical tools vs. Governance & Backing for maintenance?

Handle Negative Recommendations

- some tests are explicitly identified as useless by GL
- some RX's are contraindicated
- proper timing of a test precludes testing too early or too late

Handle Wants & Uncertainties

- Have a representation for patient inputs, especially their preferences.
- External to GL, could be utility, QALE
- Have a representation for evidence uncertainties, especially when writers advise "present patient and let them decide"
 - What to do when the GL says: at this juncture, be sure to fully counsel the patient that we don't know what to do for him or her.

Represent the Evidence

- Strength of evidence
- Estimated magnitude of benefit
- Strength of recommendation
- Handled well by USPHSTF and by ACP-ASIM in MRI for Neuro-imaging papers

Tailoring GL Issues

- Mechanism for handling common local variances
 - cheaper local services obviates or flips a cost consideration
 - some services not available (Should the GL accommodate or should the practitioner mobilize to acquire the more efficient resource?)
- How to handle the updating of a GL, when the GL has been modified by several users or purchasers?

Costs and Quality of Services

- Mechanism to include very desirable
- Costs of tests when diagnostics are equal
- Costs of RX when outcomes are equal
- Quality of services rendered must be up to performance standards
 - e.g., quality of high volume hospitals for surgeries
 - neurosurgery for carotids must include low peri-op stroke rate

Terminology & Language

- unambiguous terminology tags
- comprehensible representations
 - readability, control of expressivity
 - can show text, visual flow, programming code
 - support abstractions
 - GLIF nested subguidelines
 - abstracts that have detailed specs, e.g. what is a drug?

Work Plan for Discussion

- Use this conference list as seed
- Generate more candidate requirements
- Add to the contributions by reviewing existing GL implementation efforts
 - IHC, Duke, GHC, Kaiser, more active health plans, others
- Refine by setting boundaries & priorities
- Write draft of “specifications clarification”
- other steps?

Heterogeneous Networks

- The IPA and the medical group
- Single large site, common platform
- Multi-site, common platform
- Multi-site, multi-platform

Variety in Information Sources

- Guideline info
- Patient demographic info
- Clinical info about patient
 - medical record, lab, xray, hospital

Consider the Legal Risks

- All involved have “risk management” concerns
 - practitioners
 - their system’s diligence in adoption of GL
 - the GL vendor’s diligence
 - GL authors & reviewers
- The more automated, the more significant the risk to the vendor or author

Managing the Legal Risks

- Usual controls are contractual & licensing language
 - hold harmless, indemnify against suit
 - disclaimers putting all back on practitioner
- These are necessary parts of the business
- These inhibit “sharing” and undermine community

GLIF Conference:
Functional Requirements
Break-out #2

Dan Kent & Perry Miller, Recorders

Boston, MA
March 3-4, 2000

The Four P's

- Problems to be addressed
- Prioritize - Its all important!
- Plan - Nike sez: Just Do It!
- The People say ?

Additions from Day 2

- Transportable among collaborators
- From Level A or B in GLIF, Linkage "backwards" into reviews, refs, articles
- Version control
 - keep track of change rationale & dates
 - keep old version available
 - control national vs local modifications
 - what types of changes would lead a national sponsor disavow a guideline's local modification?

A few more

- Recommendations need to be auditable
- Allow different views for different users
 - specialist, nurse, inpt vs outpt
- consider wide variety of stakeholders, users
- Must be able to visualize GL
- Need a middle level for transportable implementation
 - like level B computable GLIF

Still More

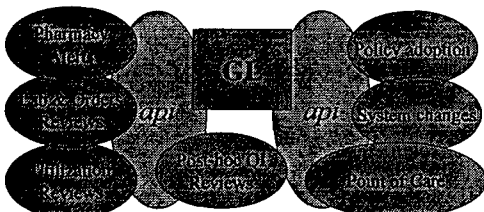
- Represent what is "standard" versus "guideline" versus "option"
 - Represent places where local users can or should make one or another design choice, e.g. which diagnostic test their institution will use
- Handle concurrent multiple GLs
 - GL representation can invoke 2 or more GLs
 - Reconcile competing or conflicting recommendations
 - maybe not reconcile but at least identify conflicts

Issues external to GL
representation

- Reconciliation of multiple GLs
- Set-up and acquisition of critiques
- Other issues that can be left external to GL
 - the method for obtaining patient preferences
 - the outcomes or care process measures for QI

Boundaries for GLs

- What to specify as within GL, versus what makes linkage of GL easier?



What we really need!

- Standardized vocabulary of weasel words
- Meta-dictionary of qualifiers and disclaimers
- A heuristic approximation of what the local guru really does when stumped by a patient
- Maybe? Peut etre?
- Go look it up!

Work Plan for Discussion

- Use this conference list as seed
- Generate more candidate requirements
- Reviewing existing GL implementation efforts
 - IHC, Duke, GHC, Kaiser, more active health plans, others
 - GLs at different stages of the life cycle diagram
- Refine by setting boundaries & priorities
- Write draft of “requirements”

Outputs or Product

- white paper
 - catalog of core requirements at each level
 - practicality? General user need?
 - What must be done first, for version 1.0?
- Categorize Requirements
 - Authoring & Development, e.g. thru GLIF-lvl A
 - Implementation & Usability, e.g. GLIF levels B,C
 - Quality & Safety, applicable to some or all stages

People

- Show me the money!
 - Cuba Gooding
- Give me the time!
 - Perry Miller

Models & Representation

John Gennari
John Fox
Paul DeClercq
Domenico Pisanelli
Gunther Schadow

What happened

- PROforma description (Fox - 10 min)
 - With cross-fire and lively discussion (20 min)
- Primitives vs. PSMs (de Clercq - 10 min)
 - With cross-fire and lively discussion (20 min)
- Ontologies (Pisanelli - 10 min)
 - With cross-fire and lively discussion (20 min)
- HL7's RIM (Schadow - 10 min)
 - With cross-fire and lively discussion (20 min)

What didn't happen

- No discussion of the GLIF model
 - GLIF 2.0 has well-known limitations
 - GLIF 3.0 is still unknown
 - Did discuss three levels: Visualization, Representation, Implementation
- No discussion of "best" models or "best" representations
 - Too early (or no interest?)
 - Did critically compare different approaches

Questions for modelers

- How abstract?
- What are the appropriate primitives?
 - Criteria & Steps: action, branch, condition
 - Action, Decision, Inquiry, Plan
 - Actions
 - Observation types: definition, event, order, goal
- How to compare representations?
- How do the three levels interact?

Next tasks

- Input from other breakouts:
 - Requirements group (level 3)
 - Tools group (level 1)
- Prioritize: Which problems are most solveable?
- Relationship to GLIF3:
 - Reasoning behind GLIF3 representational choices??
 - An opportunity for feedback!

A challenge for GLIF 3

- What are the new set of primitives?
 - Iteration, case, events, patient state, exceptions
 - Are these the right ones?
- What is the "layered" approach, and how is HL7 RIM incorporated?
- What is the representation language for expressions (criteria)?

Models & Representation

Second session

GLIF review

- Aziz bravely stood forth describing GLIF3 details
 - Steps
 - Actions
 - Decision
 - Events/exception

GLIF3 issues

- Duration of activities?
- Goals are missing
- Growth of a standard: subclassing and policies for adoption
- Need for workflow management issues

Evaluating (validation) models

- Big, difficult challenge
 - Keep us honest, grounded
 - What set of examples? What work setting?
 - Toy problems
 - Big problems (for scalability)
 - High cost of evaluation
 - Evaluating models vs. evaluating ultimate goal (sharing guidelines, looking at all three levels)

Top down, bottom up?

- Developmental strategy:
 - Start from cases, and test as you go
 - Start from theory, first principles, and test as you go.
- Can we do formal theoretic analyses of models for guidelines?

Next steps

- Motivators for getting work done:
 - Next meeting?
 - Publication opportunities (special issue of JAMIA?)
- Develop a guideline modeling community:
 - Web site, including repository
 - Example guidelines
 - White papers
 - Documentation
 - Mailing list
 - Competitions (comparisons)

Specific ideas

- Comparison studies:
 - Here's how I do X in my model, how do you do it?
 - An analysis of the static constructs of alternative models
- Report back to the community
 - White paper (or journal paper)
 - Next meeting

Issues in Clinical Trials Report from Breakout Session 1

Carol Broverman (Fast Track Systems)
Alexa McQuinn (NLM)

Guideline Workshop
March 3-4, 2003
Boston, MA

Breakout Organization

- 11 participants, including 2 moderators, 1 recorder
- Stanford, UCLA, NLM, Fast Track Systems, DSG, First Consulting, Partners Healthcare, University of London, College of London, University of Pavia
- Strategy:
 - Clinical trials is a domain area that cuts across other breakout sessions
 - Friday: Identify issues specific to clinical trials
 - Saturday breakout: raise issues in other breakouts

Distinguishing Characteristics: Clinical Trials (CT) versus Guidelines

- Commonality:
 - CT versus guidelines? Subset? Superset? Intersection? Specialization?
 - Many common elements that vary in degree of importance (decision-making, temporal issues)
- Distinguishing characteristics:
 - Strong scientific design
 - Complex visit, intra-visit-tasks, inter-visit tasks scheduled
 - Randomization (patients, providers, hospitals)
 - Data gathering critical; requirements are regulated
 - Workflow compliance is regulated

Distinguishing Characteristics (continued)

- Strict eligibility criteria
- More prescriptive nature
- Pre-anticipated workflow deviations and predefined exception handling mechanisms
- Cycles, subguidelines, iteration, looping, retrials, delays (especially in oncology)
- More granular detail
- Revisions/amendments/versioning are a given
- Double-blind studies impose requirements on "exposure" of protocol detail

Distinguishing Characteristics (continued)

- Different views: sponsor, site, patient
- Coordination intra-site and inter-organization
- Sponsor oversight/monitoring of performance of sites (especially industry)
- Patient/subject view needed also
 - Clinical trial registries that are aimed at patients
 - Instructions to subjects who are on-study
- Interim analyses required during lifetime of study

Clinical Trials Lifecycle

- Identified *Clinical Trial Lifecycle* stages with different tasks and requirements
 - Trial inception (an idea)
 - Trial design
 - Trial conduct/execution
 - Trial data collection (sometimes separate)
 - Trial data analysis
 - Trial findings feed into new trial ideas/designs
 - Trial data meta-analysis
- Presentations on trial design and NCI/CII
 - Jeremy Wyatt (UCL) and John Silva (NCI)

Next Steps

- Tasks/applications *drive* CT-specific needs
- Identify tasks within lifecycle stages
 - Functional requirements
 - Representation/model requirements
 - Tools and infrastructure requirements
 - Organizational progress/infrastructure
- CT participants to “infiltrate” breakouts
- Report on Four “Ps” this afternoon
 - Problems, Priorities, Plan, People (going forward)
- Evaluate GLIF 3.0 for CT requirements

Issues in Clinical Trials Report from Breakout Session 2

Carol Broverman (Fast Track Systems)
Alexa McClellan (NLM)

Guideline Workshop
March 3-4, 2000
Boston, MA

Task-Driven Requirements

- A representation is not self-proclaiming
- Applications/Tasks determine requirements
- Approach: enumerate tasks per life-cycle stage
- Some tasks during trial design
 - Formulation of trial, documentation of sources
 - Statistical validation (power calculation)
 - Eligibility criteria specification
 - Accrual simulation
 - Ethical review/IRB (track communication)

Task-Driven Requirements

- Some tasks during trial authoring
 - Authoring is a "supplier" to different applications/users
 - Analysis of user base and user goals required
 - Logical model to support authoring needed
 - Needs to be intuitive to clinician/knowledge engineer but must be able to capture what is needed in level 1/2
 - Mapping between different models needed (level 1/2)
 - Trial documentation exchange/reuse of text
 - Trial monitoring/compliance
 - Trial data collection

Task-Driven Requirements

- Some tasks during trial accrual
 - Matching a patient to a set of trials
 - Matching a trial to set of eligible patients
 - Formal eligibility determination
 - After Informed Consent obtained
 - Connectivity to an electronic patient record and ancillary systems (e.g.; lab, radiology) is an implied prerequisite for precision

Task-Driven Requirements

- Some tasks during trial conduct/execution
 - Monitoring visit workflow of individual patients on trial
 - Monitor visit/tasks of individual patients on trial
 - Support/Monitor data collection of individual patients
 - Inter-visit tasks and reminders
 - Generate CRFs (Case Report Forms)
 - Aggregate trial management within a site (CC/site)
 - Aggregate trial management across sites (CRA/sponsor)
 - Adverse event monitoring/reporting
 - Resource management
 - Communication/coordination (intrasite, site to sponsor)

Task-Driven Requirements

- More tasks during trial conduct/execution
 - Monitoring visit workflow of individual patients on trial
 - Support/Monitor data collection of individual patients (CRF)
 - Inter-visit tasks and reminders
 - Aggregate trial management within/across site(s)
 - Adverse event management/monitoring/reporting
 - Resource management
 - Communication/coordination (intrasite, site to sponsor)
- Tasks during trial data analysis (deferred)
- Tasks during trial meta-analysis (deferred)

Additional Considerations

- *Eligibility criteria* only hold until enrollment; separate from any “applicability criteria” that must hold at other points in lifecycle (M. Peleg)
- Requirements must consider other different designs besides randomized trials (R. Lacson)
 - Prospective cohort
 - Multi-arm, cross-over
- Consider requirements of trials per different disease/treatment areas
 - E.g.; cycles are idiosyncratic to oncology

Going Forward...

Next Steps

- Further refinement to requirements in functional areas would come from work detailing per life-cycle stage
 - Functional requirements
 - Representation requirements
 - Infrastructure requirements

More Detailed Requirements

- Further work on functional requirements
 - E.g.; what is the complete set of tasks and how to prioritize them?
- Some special representation needs?
 - E.g.; data collection visits and CRFs
 - Time windows for protocol visits/tasks
 - Uncertainty

More Detailed Requirements

- What special infrastructure requirements?
 - Authoring tool requirements
 - Dissemination of amendments
 - Versioning control/maintenance
 - Others?

P1-2: Problems (listed in Priority)

- Identify users/stakeholders
 - Expectations and requirements; solicit input
- Evaluate existing standards and requirements for protocol content and reporting
- Evaluate and extend existing representation(s)
- Create research/consortium testbed
 - E.g. Protocols authored in “standard” representation, sample test patient data....
- Build demonstration systems that use testbed
- Promote shareability and collaboration

P3-4: The Plan and People

- Resources, money and time?
- Concrete tasks for this group:
 - CT-specific discussion list (Lucila Ohno-Machado)
 - CT-specific web-site (Lucila Ohno-Machado)
 - AMIA panel participation (Carol Broverman)
 - White paper(s) describing research agenda
 - Jeremy Wyatt to take initial lead, solicit input from workshop participants
 - Aimed at informatics and clinical trials audiences

Infrastructure Group

Moderators: John Silva, Chip Masarie
Recorders: Ronilda Lacson, Lola Ogunyemi

High level summary

- Check-ins
- What is our charge?
 - Brainstorming
 - Focussing

Define infrastructure

- That which allows...
 - the ilities
 - the ables

Brainstorming

- Scalable, Integratable, Portable, Compatible, Usable, Maintanable, Adaptable, Survivable, Evolvable, Acceptable, Assures High quality input, Security, Tools, Cognitive issues,....

Requirements definition

- Prioritization

Process/Content

- Iterative refinement
- Adaptability
- Usability
- Recognizes intellectual property
- Identifiability
- Verifiability

Technology/syntax/structure

- Interoperable
- Integratable
- Portable
- Maintain/evolve/survivable
- Computational scalability

Iterative refinement

- version control
- reason for revision, justification
- allow multiple, independent development
- conflict identification
- reconciliation
- support metrics for detemining effect of change

Plan for today

- Further refinement of high level requirements

4 P's

- Problems
- Priorities
- Planning
- People

Session 2: Change of focus

- Block diagram

Authoring Tools

- May need to support multiple representation schemes
- Support multiple, concurrent authorship
- Connection to repository/libraries

Deployment Tools

- Publishing

Implementation Tools

- Allow for local modification
- Links to local interface engines

Evaluation Tools

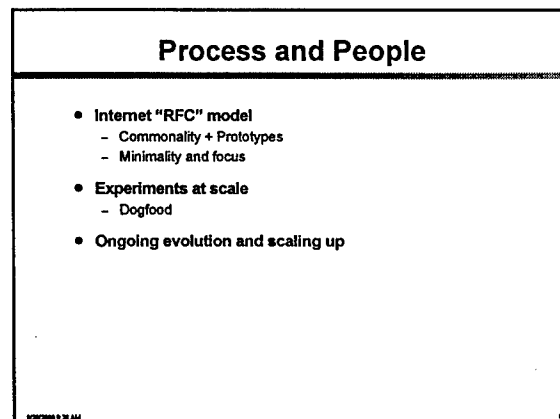
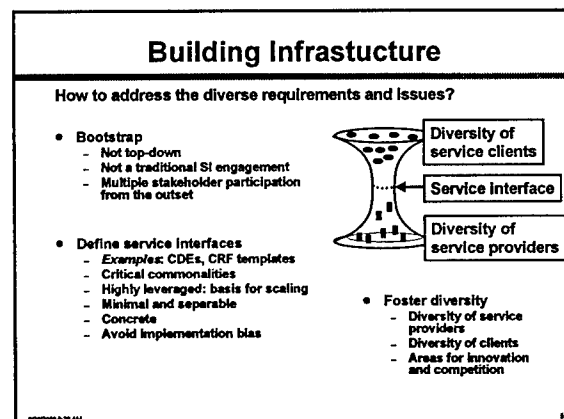
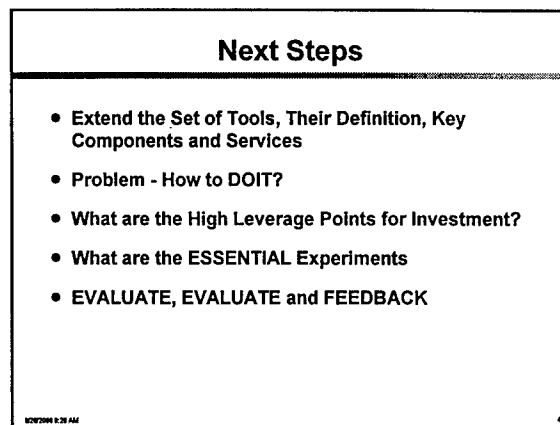
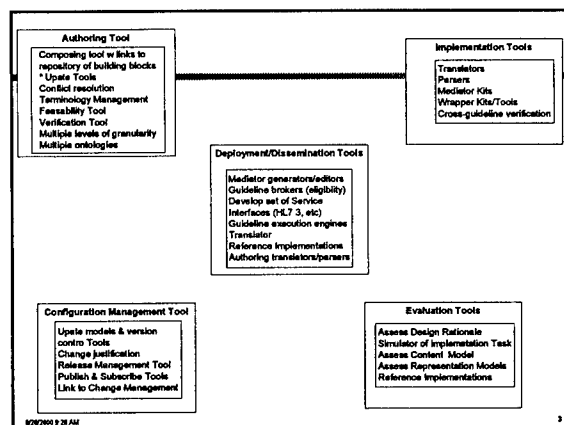
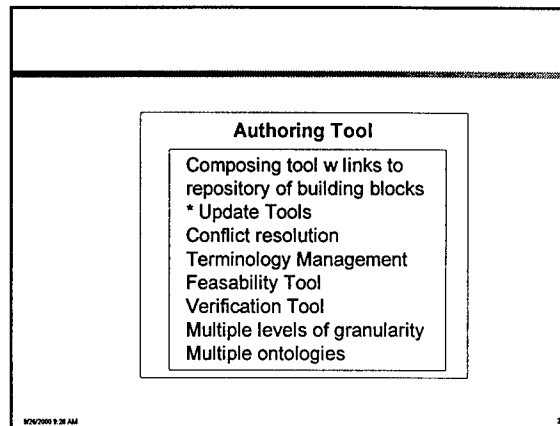
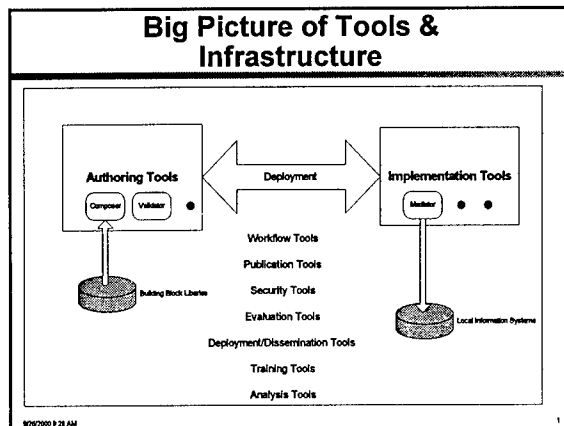
- Testing the validity of the representation scheme
- Testing to content of the guideline
- Test sets
- Usability

Configuration Management Tools

Release Management Tools

Security Tools

Training Tools



**Organization and Process
Breakout Session 1
March 3, 2000**

**Breakout Leader:
John Dulcey, M.D.**

Recorder: Robert Greenes, M.D.

Breakout Session 1 Summary

- 10 participants
- Issues addressed
 - Alternative organizational structures
 - HL7: advantages and disadvantages
 - Stakeholders
 - Next Steps

Alternative organizational structures

- Form an independent non-profit consortium
- Align with an existing SDO for specific components of guideline development
- Become a subgroup of an existing SDO
- Create a proprietary entity to seed the industry (Eg. WAP)

Advantages of HL7

- Has high visibility
- Has industry participation
- Is the sponsoring organization for Arden Syntax
- Has an established schedule of working group meetings
- Has significant international representation
- Has an established development methodology

Disadvantages of HL7

- Extra meetings for some
- Price of membership and meeting fees
- Not coincident with main mission of HL7
- Not fully international in scope

Stakeholders in Guideline Process

- Developers of content of guidelines
- Developers of tools for guideline authoring
- Guideline standards developers
- Application integrators
- Guideline users

Next Steps

- **Form a consortium of academia and industry leaders**
- **Develop a business plan that includes financial support for several full time staff to develop guidelines**
- **Look into possible industry and governmental support to finance a guideline development organization**
- **Identify participants in initial task force to move the process forward**

**Organization and Process
Breakout Session 2
March 4, 2000**

**Breakout leaders:
John Dulcey, M.D.
Peter Elkin, M.D.
Recorder: Robert Greenes, M.D.**

Strategic Planning

- **Vision**
- **Mission**
- **Values**
- **Goals**
- **Objectives**

Vision

**To create a global, sharable framework
for guideline development
and implementation.**

Mission

**Enable the widespread distribution of
health knowledge to improve health
status, improve quality and efficiency of
healthcare, and reduce health care costs.**

- Improve health care and quality of life of
world citizens through better use of medical
knowledge
- Global use of a consistent framework that
transitions between guideline development
and implementation.

Framework

- **Standards Development**
- **Mechanism for stimulating the
creation and widespread distribution
of guidelines**
- **Forum for exchange of:**
 - Ideas
 - Public domain core products

Business Plan

- **Understanding the Problems**
 - Needs
 - Solutions
- **Understanding the Opportunities**
 - Time constraints
 - Potential liaisons

Business Plan (continued)

- **Marketing**
 - Market Environment
 - Analysis of competition
 - Critical Alliances
 - Key Success Factors
 - Risk Factors

Business Plan (continued)

- **Products and Services**
 - Near term: e.g. GLIF authoring tool
 - Long term: commercial ventures
 - Proprietary vs. open source
- **Team and leadership**

Business Plan (continued)

- **Potential Funding Sources**
 - Loma Linda Testbed
 - Advanced Technology Program
 - Business Roundtable
- **Public Involvement**
 - AARP
 - UAW
 - Congress
 - White House

Next Steps

- **Write business plan**
- **Two page grant submission to Loma Linda Testbed by March 10, 2000 for authoring tool to be commercialized within two years**
- **Identify other funding sources**
- **Liaise with SDOs**
- **AMIA presentation**

Appendix D

Functional requirements for a shared guideline representation

Functional requirements for a representation for sharable guidelines

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Recent trends in health care delivery have led to an increased emphasis on the development of guidelines for prevention, diagnostic work-up, treatment, and patient-management processes. Such guidelines are motivated by concerns about marked variations in clinical practice and are designed to help to provide a common standard of care both within a health care organization and among different organizations. For better integration of guidelines into the clinical workflow, they are increasingly being disseminated and implemented using computer-based systems. The range of possible applications for computer-based guidelines is very broad, including use for disease management, encounter workflow facilitation, reminders/alerts, design and conduct of clinical trials, care plan/critical path support, appropriateness determination, risk assessment, demand management, education and training, and reference.

Computer-based approaches to representation of guidelines are being developed by various groups [1-7]. Critical to sharing of the knowledge in these guidelines across institutional, national, and medical domain boundaries would be adoption of a common format for representing them. In order to be widely usable and acceptable, such a common representation for guidelines must provide several functional capabilities. The representation must account for requirements for (a) human communication, (b) validation of logical consistency and completeness (not correctness), and (c) incorporation into institutional information system environments. We hereby propose a set of functional requirements for a sharable guideline representation language and briefly provide their underlying rationale:

1. Support for different types of guidelines. Guidelines may be classified [8] along a variety of axes such as: (a) stage of the care process, e.g., screening, diagnostic workup, and treatment; (b) the medical domain; (c) the intended application, such as in disease management, critical paths/care plans, clinical trial conduct, and appropriateness determination. Different types of guidelines may entail representations of fundamentally different concepts. For example, an appropriateness criterion that evaluates relative suitability of two diagnostic tests would represent a decision making process. A clinical trial protocol, on the other hand, represents a prescriptive patient management plan that contains concepts such as treatment visit and adverse event. The guideline representation format must be flexible to accommodate these needs.
2. Different modes of use. Encoded guidelines can potentially be used in different modes. Users

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may read or browse guidelines as educational and reference resources. Guidelines could be used interactively for patient-specific decision support and workflow support. Quality assurance applications would use guidelines as benchmarks of quality care, perhaps in a batch-processing mode. The knowledge in guidelines must be represented in a format that is independent of the expected mode of use. The representation must enable the variety of uses by structuring the knowledge in a way that will support its retrieval for all those likely uses.

3. Adaptation of guidelines for local use. Due to variations in health care settings, guidelines developed by national organizations, medical specialty organizations, or under other broad aegis often need to be modified before practitioners find them suitable for local use. Reasons for adaptation of guidelines include variations among settings due to the type of institution (e.g., hospital vs. office), location (e.g., urban vs. rural), differential availability of equipment and medications, dissimilarity of patient population (e.g., as reflected in prevalence of the disease), and local policies and workflow patterns. A common representation format must provide the ability to adapt knowledge contained in guidelines, and track and document modifications to the guideline.
4. Integration with institutional systems. For integrating guidelines into the clinical workflow, references to patient data and clinical actions in guidelines will need to be mapped to their instantiations or implementations in heterogeneous clinical information systems environments. This requirement implies the use of standard vocabularies and standard reference data models by the guideline representation format, which mapping tools can utilize to achieve the integration.
5. Revision tracking. Guidelines are often revised in response to changing medical knowledge. The representation format must keep track of and document revisions to the guideline. Among other reasons, revision tracking is important for incorporating new versions of externally developed guidelines into institutional use.
6. Managing complexity. Guidelines and their logic may get fairly complex. The representation format must deal with this complexity by abstracting details into high-level concepts. The management of complexity in representation is important during authoring and viewing of guideline.

The InterMed project, a collaboration among medical informatics groups at Stanford, Harvard, McGill, and Columbia universities, supported by the National Library of Medicine, developed a representation for sharable clinical guidelines. The initial version of the representation, known as the Guideline Interchange Format (GLIF), was published in 1998. A follow-on project, funded by both the NLM and the US Army, brings together investigators at Harvard, Stanford, Columbia, and McGill, with guideline developers from the American College of Physicians-American Society of Internal Medicine, to further define guideline representation requirements so as to facilitate authoring, sharing, and integration into applications. The requirements stated above are a result of our experience with the development and use of GLIF, and form the basis for refinements being made to the GLIF specification.

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REPLY TO
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MCMR-RMI-S (70-1y)

18 Apr 03

MEMORANDUM FOR Administrator, Defense Technical Information
Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir,
VA 22060-6218

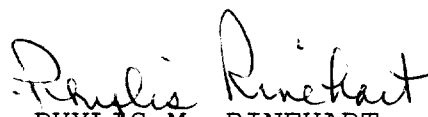
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1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

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